U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Health Resources and Services Administration

HIV/AIDS Bureau
Special Projects of National Significance Program

Enhancing Engagement and Retention in Quality HIV Care for Transgender Women of Color – Evaluation and Technical Assistance Center

Announcement Type: New Competition
Announcement Number: HRSA-12-101

Catalog of Federal Domestic Assistance (CFDA) No. 93.928

FUNDING OPPORTUNITY ANNOUNCEMENT

Fiscal Year 2012

Application Due Date: *April 16, 2012*

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Release Date: *February 16, 2012*

Issuance Date*: February 16, 2012*

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Authority: Public Health Service Act, Section 2691 (42 USC 300ff-101), as amended by the Ryan White HIV/AIDS Treatment Extension Act of 2009 (P.L. 111-87)

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I. Funding Opportunity Description

1. Purpose

This funding opportunity announcement solicits applications for the *Enhancing Engagement and Retention in Quality HIV Care for Transgender Women of Color – Evaluation and Technical Assistance Center,* for a new Special Projects of National Significance (SPNS) Program multi-site initiative. Under this funding opportunity announcement, a cooperative agreement will be issued to support one organization for up to five years to evaluate and provide technical assistance and capacity building for up to eight demonstration projects funded under a separate announcement, *Enhancing Engagement and Retention in Quality HIV Care for Transgender Women of Color – Demonstration Sites* (HRSA-12-099). Organizations that apply under this announcement may not also apply under the Demonstration Sites announcement.

The demonstration projects will design, implement and evaluate innovative interventions designed to improve timely entry, engagement and retention in quality HIV care for transgender women of color living with HIV infection. The primary focus of this initiative is to identify and successfully engage and retain in care transgender women of color who are at high risk of HIV infection or are infected with HIV but are unaware of their HIV status; are aware of their HIV infection but have never been engaged in care; are aware but have refused referral to care; or have dropped out of care.

The Evaluation and Technical Center (ETAC) will be expected to fulfill four important functions for this SPNS initiative. The ETAC will 1) provide technical assistance to the demonstration projects over the course of the initiative; 2) serve as a capacity building resource for clinical care and cultural competency for the demonstration projects; 3) conduct a rigorous multi-site evaluation of the implementation and outcomes of all interventions and the multi-site cohort as a whole; and 4) lead and coordinate the efforts for publication and dissemination of findings and lessons learned from the initiative. The ETAC will work in close consultation with the SPNS program in all aspects of the initiative, but especially in the implementation of the multi-site evaluation.

The successful applicant will demonstrate expertise in both engagement and retention in HIV treatment and in transgender health issues. Applications should include a literature review that demonstrates an in-depth understanding of the trangender population and the challenges involved in identifying transgender women of color who are unaware of their HIV status, as well as engaging and retaining those newly diagnosed in quality HIV primary care. Applicants should discuss the many patient-level barriers to accessing care encountered by transgender women of color, including but not limited to discrimination in employment, housing and health care; physical and sexual violence; economic vulnerability; housing instability and homelessness; substance abuse; depression and suicidality; competing access to care and life priorities; and culturally-specific racial and ethnic differences such as language barriers and immigration status. Applicants should also discuss the factors driving HIV incidence and prevalence rates among transgender women of color using the most recent, available, *transgender*-specific data (i.e., non-MSM).

According to the Centers for Disease Control and Prevention (CDC), national HIV incidence in the United States is now relatively stable. An alarming exception to this stability are the increasingly higher annual incidence rates in young men who have sex with men (YMSM) and in particular, African-American YMSM.[1] CDC also estimates that 21 percent of the 1,106,400 adults and adolescents living with HIV in the U.S. at the end of 2006 were unaware of their infection.[2] Those unaware account for over half of new sexually transmitted HIV infections, with transmission rates 3.5 times higher than those who are aware.[3] Additionally, as many as one third of those previously diagnosed and aware of their HIV infection remain out of care,[4] often for years.[5] Timely entry into HIV care post-diagnosis has been found to have a number of benefits, including decreased morbidity, mortality and infectiousness,[6] as well as exposure to effective secondary prevention efforts through cost-effective clinical interventions.[7,8] There are many reasons why HIV-positive persons may delay entering care upon diagnosis, including structural, financial and personal/cultural barriers arising from racial, ethnic and gender disparities.[9] Continuous retention in care has benefits similar to those of timely entry, and a number of strategies have been developed to promote retention such as intensive case management, patient navigation, peer support groups, and mobile van outreach to find clients who were lost to follow-up.[9, 10]

The National HIV/AIDS Strategy (NHAS[11]) released in July 2010 by the White House Office of National AIDS Policy has three primary goals: 1) reducing the number of people who become infected with HIV, 2) increasing access to care and optimizing health outcomes for people living

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[1] Prejean J, Song R, Hernandez A, et al. Estimated HIV incidence in the United States, 2006-2009. *PLoS ONE*. 2011; 6 (8): e17502. E-published August 3, 2011.

[2] Campsmith ML, Rhodes PH, Hall HI, & Green TA. Undiagnosed HIV Prevalence Among Adults and Adolescents in the United States at the End of 2006. *Journal of Acquired Immune Deficiency Syndromes*, 2010 April; 53 (5): 619-624.

[3] Marks G, Crepaz N, & Janssen RS. Estimating sexual transmission of HIV from persons aware and unaware that they are infected with the virus in the USA. *AIDS,* 2006 June; 20 (10): 1447-50140.

[4] Fleming PL, Byers RH, Sweeney PA, et al. HIV prevalence in the United States, 2000. Presented at the 9th Conference on Retroviruses and Opportunistic Infections, February 24-28, 2002, Seattle, WA.

[5] Samet JH, Freedberg KA, Savetsky JB, et al. Understanding delay to medical care for HIV infection: the long-term non-presenter. *AIDS,* 2001 January, 15 (1): 77-85.

[6] Department of Health and Human Services, Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in HIV-1-infected Adults and Adolescents, pages 27-32. Department of Health and Human Services. October 14, 2011. Available from: http://aidsinfo.nih.gov/contentfiles/AdultandAdolescentGL.pdf

7 Myers JJ, Shade SB, Rose CD, et al. Interventions Delivered in Clinical Settings are Effective in Reducing Risk of HIV Transmission Among People Living with HIV: Results from the Health Resources and Services Administration (HRSA)'s Special Projects of National Significance Initiative. *AIDS and Behavior*, 2010 June; 14 (3): 483-492.

[8] Marseille E, Shade SB, Myers J, & Morin S. The cost-effectiveness of HIV prevention interventions for HIV-infected patients seen in clinical settings. *Journal of Acquired Immune Deficiency Syndromes,* 2011 March; 56 (3): e87-e94.

[9] Tobias C, Cunningham WE, Cunningham CO, & Pounds MB. Making the Connection: The Importance of Engagement and Retention in HIV Medical Care. *AIDS Patient Care & STDs,* 2007; 21 (Supplement 1): S3-S8.

[10] Gardner L, Marks G, Metsch L, et al. Psychological and Behavioral Correlates of Entering Care for HIV Infection: The Antiretroviral Treatment Access Study (ARTAS) *AIDS Patient Care and STDs,* 2007; 21 (6): 418-425.

[11] Office of National AIDS Policy (2010) National HIV/AIDS Strategy for the United States. ONAP, The White House. Available from: http://www.whitehouse.gov/sites/default/files/uploads/NHAS.pdf

with HIV, and 3) reducing HIV-related health disparities. The NHAS states that more must be done to ensure that new prevention methods are identified and that prevention resources are more strategically deployed. Further, the NHAS recognizes the importance of getting people with HIV into care early after infection to protect their health and reduce their potential of transmitting the virus to others. HIV disproportionately affects people who have less access to prevention and treatment services and, as a result, often have poorer health outcomes. The NHAS thus advocates adopting community-level approaches to reduce HIV infection in high-risk communities and reduce stigma and discrimination against people living with HIV. To ensure success, the NHAS requires the Federal government and State, tribal and local governments to increase collaboration, efficiency, and innovation. Therefore, to the extent possible, Ryan White program activities should strive to support the three primary goals of the National HIV/AIDS Strategy.

The NHAS's first primary goal of reducing new HIV infections includes an actionable step of *intensifying HIV prevention efforts in communities where HIV is most heavily concentrated*, and identifies *gay and bisexual men and transgender individuals* as high-risk target populations.[12] Another actionable step under this goal is *expanding targeted efforts to prevent HIV infection*, with recommended actions including (2.2) *strengthening HIV screening and surveillance activities to identify populations at greatest risk that need to be targeted for HIV prevention services* and (2.4) *expansion of prevention with HIV-positive people.* [13]

CDC does not yet report HIV surveillance data for transgender people, who have been classified as Men who have Sex with Men, but may do so in the future.[14] However, CDC has published some data that suggests transgender people are at high risk for HIV/AIDS, and many may be living with HIV infection. In 2000, CDC reported an outbreak of HIV-related Tuberculosis among MSM in the House Ball Communities of Baltimore, MD; Jersey City, NJ; and New York City. House Balls are competitive performance events frequented by MSM and transgender persons, and CDC found an HIV prevalence rate of 62 percent among the 26 TB case patients.[15] Also in 2000, CDC reported that transgender persons had the highest HIV prevalence among all reported sexual identities in the 1994-1998 Young Men's Study. HIV prevalence among young transgender persons (14.3 percent) was almost twice that of young gay men (7.5 percent).[16] In 2005, CDC reported the prevalence of newly identified HIV infections was highest among persons in social networks recruited by transgender persons (20 percent), followed by MSM (14.9 percent).[17] In 2011, CDC responded to this increasing HIV incidence among youth by awarding $55 million over five years to 34 community-based organizations for HIV prevention targeting both young MSMs and young Transgender Persons of Color.[18]

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[12] NHAS, p.15

[13] NHAS, p. 19

[14] CDC. HIV among Transgender People Fact Sheet, August 2011.

[15] CDC. HIV-related tuberculosis in a transgender network-Baltimore, Maryland, and New York City area, 1998-2000. Morbidity and Mortality Weekly Report, 2000; 49 (15): 317-320.

[16] Valleroy LA, MacKellar DA, Karon JM, et al. HIV prevalence and associated risks in young men who have sex with men. Young Men's Survey Study Group. *Journal of the American Medical Association,* 2000;284: 198–204.

[17] CDC. Use of Social Networks to Identify Persons with Undiagnosed HIV Infection — Seven U.S. Cities, October 2003–September 2004. Morbidity and Mortality Weekly Report, 2005; 54 (24): 601-605.

[18] CDC. Funding Opportunity Announcement (FOA) PS11-1113: Human Immunodeficiency Virus (HIV) Prevention Projects for Young Men of Color Who Have Sex with Men and Young Transgender Persons of Color.

Absent core surveillance data, much of what is known about HIV infection among transgender persons has been gained through urban health department and community-driven needs assessment surveys and risk behavioral studies using mostly convenience sampling. CDC's Prevention Research Synthesis Team conducted a meta-analysis of these studies, and in the 22 studies that reported HIV status, estimated HIV prevalence among transgender women was almost 12 percent by participants in 18 studies who self-reported their status.[19] However, estimated prevalence for those who were actually HIV-tested in 4 studies was nearly 28 percent, suggesting that between 45 to 65 percent of HIV positive transgender women are unaware of their HIV status. These data are comparable to a 1998 study of 515 transgender people in San Francisco that found 35 percent of those testing positive were unaware of their HIV positive status.[20]

Therefore, there is an apparent emerging need for increased HIV testing among transgender people. In an analysis of national testing data from 2009, CDC reported that the highest rate of newly identified confirmed HIV infection was among transgender persons (2.6 percent, compared with 0.9 percent among males and 0.3 percent among females). However, only 4,112 of the 2,620,877 persons tested – less than 2/10s of 1 percent – were transgender persons.[21] Although the health departments of California, Los Angeles, San Francisco and New York have reported transgender-specific HIV testing data,[22, 23, 24, 25] other health departments have yet to follow their lead. Two earlier studies also reported high incidence rates of new HIV infections for transgender women in San Francisco in 2001 (7.8 infections per 100 person years)[26] and in Los Angeles in 2000 (3.4 infections per 100 person years).[27]

HIV prevalence and incidence among transgender women may parallel that of MSM, with the highest rates found among those of color. In previous research, African-American transgender women had been found to have the highest HIV prevalence rates, ranging from 41 to 63 percent.

[19] Herbst J, Jacobs E, Finlayson T, et al. Estimating HIV prevalence and risk behaviors of transgender persons in the United States: A systematic review. *AIDS and Behavior*, 2008 January;12 (1): 1-17.

[20] Clements-Nolle K, Marx R, Guzman R, et al. HIV prevalence, risk behaviors, health care use, and mental health status of transgender persons: Implications for public health intervention. *American Journal of Public Health*, 2001 June; 91(6): 915-921.

[21] CDC. *HIV Testing at CDC-Funded Sites, United States, Puerto Rico, and the U.S. Virgin Islands, 2008-2009.* Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention; July 2011.

[22] California Department of Public Health. HIV/AIDS Surveillance Reports. 2010 Quarterly HIV/AIDS Statistics, Cases Reported as of December 31, 2010, Table 2.

[23] San Francisco Department of Health. Quarterly HIV/AIDS Surveillance Report – HIV/AIDS Cases Reported Through June 2011.

[24] Los Angeles County Public Health Department. 2010 Annual HIV Surveillance Report.

[25] New York City Department of Health and Mental Hygiene. HIV among Transgender Persons in New York City, 2005–2009. NYC DOHHM, Epidemiology & Field Services, February 2011.

[26] Kellogg T, Clements-Nolle K, Dilley J, et al. Incidence of Human Immunodeficiency Virus Among Male-to-Female Transgender Persons in San Francisco. *Journal of Acquired Immune Deficiency Syndrome*, 2001 December; (4): 381-384.

[27] Simon P, Reback C, & Bemis C. HIV prevalence and incidence among male-to-female transsexuals receiving HIV prevention services in Los Angeles County. *AIDS,* December 22, 2000; 14 (18): 2953-2955.

[27, 28, 29, 30, 31] Among Latinas, HIV prevalence has ranged from 14 to 50 percent, [27, 28, 30, 31, 32] and from 4 to 27 percent among Asian-Pacific Islander transgender women.[33,34,35] In 2009, CDC conducted a three city Transgender HIV Behavioral Surveillance study which identified significant levels of unprotected sex with male partners, sex work and homelessness among African-American and Latina transgender women.[36, 37]

Young transgender women and young MSM also share similar HIV risk factors, including unsafe sexual behaviors and substance abuse. In two studies of HIV among young transgender women, HIV prevalence ranged from 19 to 22 percent. [38, 39] Exchange sex has been reported among YMSM, and many transgender youth engage in survival sex where sexual behavioral risks increase.[40,41] Unlike MSM, female gender identity affirmation through unprotected sex with male partners has been identified as an HIV/ STD risk factor among transgender women.[42, 43] Transgender women also experience HIV and Hepatitis C transmission risks through needle sharing from injection drug use,[44,45,46] and hormones and silicone injections.[45,47]

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[28] Clements-Nolle et al, 2001

[29] Rose V, Scheer S, Balls J, et al. Investigation of the High HIV Prevalence in the Transgender African American Community in San Francisco. UCSF Center for AIDS Prevention Studies. Poster # TuOrE1157, presented at the XIV International AIDS Conference in Barcelona, Spain, July 2002.

[30] Nemoto T, Operario D, Keatley J, et al. HIV risk behaviors among male-to-female transgender persons of color in San Francisco. *American Journal of Public Health*, 2004 July; 94(7): 1193-99.

[31] Nuttbrock L, Hwahng S, Bockting W, et al. Lifetime risk factors for HIV/sexually transmitted infections among male-to-female transgender persons. *Journal of Acquired Immune Deficiency Syndromes*, 2009 Nov; 52(3): 417-21.

[32] Rodríquez-Madera S, Toro-Alfonso J. Gender as an obstacle in HIV/AIDS prevention: Considerations for the development of HIV/AIDS prevention efforts for male-to-female transgenders. *International Journal of Transgenderism*, 2005; 8(2/3):113-22.

[33] Clements K, Katz M, & Marx R. *The Transgender Community Health Project: Descriptive Results.* San Francisco Department of Public Health, February 18, 1999.

[34] Simon et al, 2000.

[35] Nemoto et al, 2004.

[36] Carlos J, Padgett P, & Bingham T. *HIV Behavioral Surveillance among Black and Latina Transgender Women in Los Angeles County.* Abstract # 22381, 138th Annual Meeting of the American Public Health Association, Denver, CO, November 10, 2010.

[37] Padgett P & Risser J. *Transgender HIV Behavioral Surveillance (THBS) pilot study in Houston, TX.* Abstract # 223863, 138th Annual Meeting of the American Public Health Association, Denver, CO, November 10, 2010.

[38] Wilson E, Garofalo R, Harris R, et al. Transgender female youth and sex work: HIV risk and a comparison of life factors related to engagement in sex work. *AIDS and Behavior*, 2009 October; 13(5): 902-13.

[39] Garofalo R, Deleon J, Osmer E, et al. Overlooked, misunderstood and at-risk: Exploring the lives and HIV risk of ethnic minority male-to-female transgender youth. *Journal of Adolescent Health*, 2006 March; 38(3): 230-36.

[40] Gwadz M, Clatts M, Leonard N, & Goldsamt L Attachment Style, Childhood Adversity, and Behavioral Risk Among Young Men Who Have Sex With Men. *Journal of Adolescent Health,* 2004 May; 34 (5): 402–413.

[41] Belzer M & Radzik M. High Risk Characteristics in a Cohort of HIV infected and Noninfected Transgender Youth. Abstract for presentation at the Annual Meeting of The Society for Adolescent Medicine, March 1997, in *Journal of Adolescent Health,* 1997 February; 20 (2): 156.

[42] Bockting WO, Robinson BE, & Rosser BR. Transgender HIV prevention: A qualitative needs assessment. *AIDS Care*, 1998 August; 10(4): 505-525.

[43] Nemoto T, Operario D, Keatley J, & Villegas D. Social context of HIV risk behaviours among male-to-female transgenders of colour. *AIDS Care*, 2004 August; 16 (6): 724–735.

[44] Clements-Nolle et al., 2001

[45] Risser J, Shelton A, McCurdy S, et al. Sex, Drugs, Violence, and HIV Status Among Male-to-Female Transgender Persons in Houston, Texas. *International Journal of Transgenderism*, 2005; 8 (2/3): 67-74.

The second primary goal of the NHAS is to increase access to care and improve health outcomes for people living with HIV.[48] Despite high rates of HIV prevalence, incidence and risk behaviors identified in research, there is evidence suggesting a treatment gap exists among transgender women living with HIV/AIDS. A four-city study using data from the National Institute of Mental Health's Healthy Living Project found that transgender women were less likely to receive Highly Active Anti-Retroviral Therapy compared with a control group of MSM, heterosexual women and men, and male intravenous drug users.[49] According to 2008 data from the Ryan White HIV/AIDS Program, only 6,328 transgender clients received Ryan White services nationwide, and only 365 were enrolled in ADAP Programs.[50] A 2002 study using data from HRSA's Client Demonstration Project found that compared to male Ryan White clients, transgender clients were 85 to 90 percent less likely to engage or remain in safety net-funded primary medical care.[51] CDC's Medical Monitoring Project, which assesses clinical and behavioral outcomes among HIV-infected persons, found that among 898 participants of its pilot cycle (6 States and 3 cities) only 15 (less than 2 percent) were transgender persons.[52]

With regard to access to care, the NHAS states that *being linked to care is not enough. It is estimated that as many as 30 percent of people diagnosed with HIV are not accessing care. There is a need to re-engage people diagnosed with HIV who have never been in care or who have subsequently fallen out of care.*[53] Furthermore, *transgender individuals are particularly challenged in finding providers who respect them and with whom they can have honest discussions about hormone use and other practices, and this results in lower satisfaction with their care providers, less trust, and poorer health outcomes.*[54]

There is considerable evidence that transgender people experience difficulties when attempting to access health care. Discrimination by health care providers who have denied medical care to transgender people has been reported in six studies ranging from 11 to 53 percent.[55,56,57,58,59,60]

[46] McGowan CK. *Transgender Needs Assessment, December 1999*. The HIV Prevention Planning Unit of New York City Department of Health and Mental Hygiene.
[47] New York City Department of Health and Mental Hygiene. Health Department Warns that Cosmetic Injections from Unlicensed Practitioners Can Cause Serious Health Effects and Death. NYCDOHMH, April 17, 2009.
[48] NHAS, p.21
[49] Melendez R, Exner T, Ehrhardt A, et al. Health and health care among male-to-female transgender persons who are HIV positive. *American Journal of Public Health,* 2006 June; 96 (6): 1034-1037.
[50] Health Resources and Services Administration (HRSA) *Going the distance—The Ryan White HIV-AIDS Program, 20 years of leadership, a legacy of care*, p.42 & 51. U.S. Department of Health and Human Services, Health Resources and Services Administration, HIV AIDS Bureau; 2010 August.
[51] Ashman J, Conviser R & Pounds M. Associations between HIV-positive individuals' receipt of ancillary services and medical care receipt and retention. *AIDS Care, 14* (Supplement 1): S109–S118.
[52] CDC. Clinical and Behavioral Characteristics of Adults Receiving Medical Care for HIV Infection: Medical Monitoring Project, 2005 Pilot Data Collection Cycle. HIV Special Surveillance Report 6, June 2010.
[53] NHAS, p.24
[54] NHAS, p.26
[55] Xavier J, Honnold J, and Bradford J. The Health, Health-Related Needs, and Lifecourse Experiences of Transgender Virginians. Richmond, VA: Virginia HIV Community Planning Committee and Virginia Department of Health: 2007.
[56] Reback et al, 2001.
[57] Kenagy G. The health and social service needs of transgender people in Philadelphia. *International Journal of Transgenderism,* 2005: 8(2/3):49-56.

For many transgender people, simply disrobing for a physical exam places them in an unsafe situation. Past experiences with provider insensitivity and hostility can produce intense fears of disclosure of transgender status, causing many to avoid the health care system altogether.[61,62,63, 64, 65,66,67,68] High rates of joblessness and poverty among transgender people, especially those of color and transgender youth, often result in a lack of health insurance or underinsurance.[64, 65,69, 70, 71] Percentages of transgender people who lack health insurance have been reported as ranging from 21 to 64 percent in studies conducted in 9 cities [61, 64, 71, 72, 73,74,75,76,77] and from 13 to 27 percent in 2 states.[62,69] Accordingly, participants in a 2005 community consultation meeting conducted by HRSA's HIV/AIDS Bureau recommended funding a SPNS project focused on transgender people to develop treatment interventions for this population.[78]

For the purposes of this funding opportunity announcement, *transgender* is defined as a term to describe a person whose self-reported gender identity does not correspond with their assigned physical sex at birth. *Transgender women* is used in this announcement to describe natal males with female gender identities and/or feminine gender expressions. *Transgender women of color* describes those who identify as belonging to one or more of the following racial and ethnic

[58] Kenagy G, and Bostwick W. Health and social service needs of transgendered people in Chicago. *International Journal of Transgenderism*, 2005; 8(2/3):57-66.

[59] FTM (Female-to-Male) Alliance of Los Angeles. Results of the 2003 health access survey. Los Angeles, CA: FTM Alliance, 2004.

[60] Transgender Law Center. The State of Transgender California Report—Results from the 2008 California Transgender Economic Health Survey. San Francisco: Transgender Law Center; 2009.

[61] Kenagy & Bostwick, 2005

[62] Transgender Law Center, 2009

[63] Sperber J, Landers S, & Lawrence S. Access to health care for transgendered persons: Results of a needs assessment in Boston. *International Journal of Transgenderism*, 2005; 8(2/3): 74-91.

[64] Xavier J, Bobbin M, Singer B, & Budd E. A needs assessment of transgendered people of color living in Washington, DC. *International Journal of Transgenderism*, 2005; 8(2/3): 31-47

[65] Garofalo R et al, 2006

[66] Zians J. The San Diego County transgender assessment report. San Diego: Family Health Centers of San Diego, CA; 2006.

[67] Kammerer N, Mason T, Connors M, & Durkee R. Transgender health and social service needs in the context of HIV risk. *International Journal of Transgenderism*, 1999; 3 (1+2).

[68] Clements K, Wilkinson W, Kitano K, et al. HIV prevention and health service needs of the transgender community in San Francisco. in Bockting W & Kirk S, editors (2001) *Transgender and HIV: Risks, Prevention and Care*, 49-89. Binghamton, NY: Haworth Press.

[69] Xavier et al, 2007

[70] Risser et al, 2005

[71] McGowan, 1999

[72] Reback et al, 2001

[73] Zians, 2006

[74] Carson L. Physical and emotional health needs of transgender individuals living in Philadelphia: Summary of key findings. Philadelphia: Public Health Management Corporation, 2009.

[75] Cambridge Cares About AIDS. Transgender Care and Education Needs Diversity (TransCEND) community needs assessment report. Cambridge, MA: Cambridge Cares About AIDS, 2006.

[76] Clements-Nolle et al, 2001

[77] Odo & Hawelu, 2001

[78] Health Resources and Services Administration. HIV/AIDS in the Transgender Population: A Community Consultation Meeting. HRSA, HIV/AIDS Bureau, Division of Community Based Programs, May 5, 2005. Available from: http://www.careacttarget.org/library/TransgenderReport.pdf

categories established by the Office of Management and Budget's Standards for Data on Race and Ethnicity[79] and used by the U.S. Census Bureau: American Indian or Alaska Native; Asian; Black or African American; Hispanic or Latino; or Native Hawaiian or Other Pacific Islander. Although transgender women of color living with HIV infection are the primary target population for the multi-site evaluation of this initiative, this definition does not preclude the provision of services under this initiative to persons of any race, ethnicity, sex, sexual orientation, or gender identity. Other populations of interest include other transgender women, transgender men, and other gender non-conforming persons at risk or living with HIV/AIDS.

Ryan White Parts A, B and C –funded organizations are required to describe their strategies, plans and data for the Early Identification of Individuals with HIV/AIDS (EIIHA), which is defined as *the identifying, counseling, testing, informing, and referring of diagnosed and undiagnosed individuals to appropriate services, as well as linking newly diagnosed HIV positive individuals to medical care.*[80] This initiative will use the 2011 EIIHA definition of those who are unaware of their HIV status as *any individual who has not been tested for HIV in the past 12 months, or any individual who has not been informed of their HIV test result (HIV positive or HIV negative), or any HIV positive individual who has not been informed of their confirmatory HIV test result*.[81]

Defining exactly what is meant by being linked to and retained in HIV primary care services can become complex. The HIV/AIDS Bureau conducted an expert consultation meeting in 2005 focusing on outreach efforts to engage HIV-infected persons in care, and later published a report[82] containing an engagement in care continuum model intended to assist service providers and policymakers design programs to meet variable client needs (see Figure 1). At one end of the continuum are those who are completely unaware of their HIV status and thus not in care, while those fully engaged in continuous HIV care are at the other end. In between are various degrees of engagement. Ideally, HIV-infected persons would progress from learning they are HIV positive to immediate linkage to HIV primary care to maintaining full engagement in that care. However, the reality is quite different, and research has shown that Ryan White clients may move through different stages along the continuum at various times in their lives.

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[79] Office of Management and Budget. Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity – Appendix A (Excerpt from *Federal Register*, October 30, 1997). Available from: http://www.whitehouse.gov/sites/default/files/omb/assets/information_and_regulatory_affairs/re_app-a-update.pdf

[80] See page 19 of the 2012 Part A Funding Opportunity Announcement (HRSA-12-128) at: https://grants.hrsa.gov/webExternal/FundingOppDetails.asp?FundingCycleId=E968A587-A1B4-49B7-8BF9-2AFD963BDE20&ViewMode=EU&GoBack=&PrintMode=&OnlineAvailabilityFlag=True&pageNumber=1&Popup=#Purpose

[81] See page 16 of the 2011 Part B Funding Opportunity Announcement (HRSA-11-061) at: https://grants.hrsa.gov/webExternal/FundingOppDetails.asp?FundingCycleId=4012E24E-92BC-400C-94CF-0D63436711D8&ViewMode=EU&GoBack=&PrintMode=&OnlineAvailabilityFlag=&pageNumber=&version=&NC=&Popup=

[82] Health Resources and Services Administration, HIV/AIDS Bureau. August 2006. Outreach: Engaging People in HIV Care Summary of a HRSA/HAB 2005 Consultation on Linking PLWH Into Care. Accessed 10/12/11 from ftp://ftp.hrsa.gov/hab/HIVoutreach.pdf

Figure 1: Engagement in Care Continuum

Not in Care ⟵⟶ **In Care**

Unaware of HIV Status (never tested or never received results)	Know HIV Status (not referred to care or didn't keep referral)	May Be Receiving Other Medical Care But Not HIV Care	Entered HIV Primary Medical Care but Dropped Out (lost to follow-up)	In and Out of HIV Care or Infrequent User	Fully Engaged in HIV Primary Medical Care (linked to care)
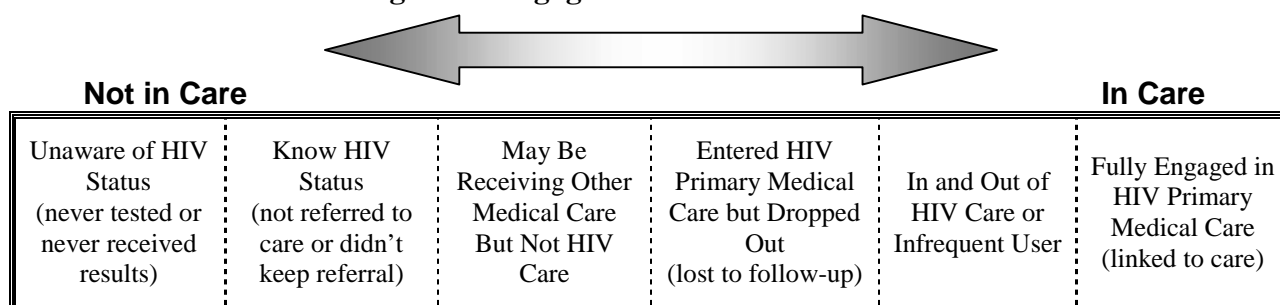
2. Background

The Special Projects of National Significance (SPNS) Program is authorized by Section 2691 of the Public Health Service Act, as amended by the Ryan White HIV/AIDS Treatment Extension Act of 2009 (P.L. 111-87) referred hereafter as the Ryan White HIV/AIDS Program. The SPNS Program supports the development of innovative models of HIV care to quickly respond to the emerging needs of clients served by the Ryan White HIV/AIDS Programs. The SPNS Program also evaluates the effectiveness of these models' design, implementation, utilization, cost, and health related outcomes, while promoting the dissemination and replication of successful models.

II. Award Information

1. Type of Award

Funding will be provided in the form of a cooperative agreement. A cooperative agreement, as opposed to a grant, is an award instrument of financial assistance where substantial involvement is anticipated between HRSA and the recipient during performance of the contemplated project.

In addition to the usual monitoring and technical assistance provided under grants, HRSA SPNS Program responsibilities under the terms of this cooperative agreement will include the following:

- Making available the services of experienced HRSA/HAB personnel as participants in the planning and development of all phases of the project;
- Ongoing review of activities, procedures, measures, and tools to be established and implemented for accomplishing the goals of the cooperative agreement;
- Participation in conference calls, meetings and conferences to be conducted during the period of the cooperative agreement;
- Provision of information resources;
- Review and approval of all project information prior to dissemination; and
- Participation in the dissemination of project findings, best practices and lessons learned.

The cooperative agreement recipient's responsibilities shall include:

1) Provide Technical Assistance

The ETAC will provide technical assistance (TA) to the demonstration projects for a range of needs over the course of the entire initiative. ETAC applicants must proposed a means of routine assessment of the TA needs of the demonstration projects, to include a formatted regular report to SPNS staff. The ETAC will be expected to provide technical assistance during regular teleconferences; through its website and webinars; during annual site visits; and at the twice-a-year SPNS grantee meetings across the following domains:

a) Program Development, Implementation and Sustainability. The ETAC will monitor, assess, and identify areas of need in the development and implementation of demonstration project interventions. When appropriate, the ETAC will provide remedial TA for issues such as counseling and testing; provision of intervention-related outreach, case management, peer education, patient navigation, and other engagement and retention activities; referral network development, expansion and maintenance; project promotion and participant recruitment; and resources for staff training for interventions that incorporate existing interventions (DEBIs, etc.) and/or use peer educators and patient navigators. Although prevention interventions such as the DEBIs[83] may be incorporated into a demonstration site project, the goals of these interventions must focus on the identification, engagement and retention of transgender women of color living with HIV infection in care. The ETAC also will provide resources related to sustaining the interventions beyond the SPNS funding, including third party reimbursement and additional public and private funding streams and opportunities.

b. Clinical Consultation. The ETAC will be expected to provide clinical consultation at the request of demonstration projects regarding HIV treatment and transgender health issues though telecommunications and during site visits. Special attention should be given to the interactions between ART medications and transgender hormones. The ETAC must include in its staffing plan physician(s) who are competent in both HIV primary care and transgender health to provide this clinical consultation.

c. Multi-site and Local Evaluation. The ETAC will be expected to assist the demonstration projects in implementing its multi-site evaluation plan, to include but not limited to training demonstration project staff in the use of the data collection instruments and web-based data entry portal; regular monitoring of data collection and reporting efforts by the demonstration projects; and remedial action when necessary to assure data collection of the highest quality. Demonstration projects will be expected to conduct local evaluations to assess the effectiveness of their interventions, and the ETAC will serve as a resource for refining the designs and monitoring the implementation of their local evaluation plans to assure their rigor and quality.

d. Human Research Subjects Protection. The requisite collection of client-level data for this SPNS initiative will require diligent efforts to assure the privacy and confidentiality of project participants, their medical records and their health-seeking efforts. The ETAC will be expected

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[83] See http://www.effectiveinterventions.org/

to lead these efforts and guide the demonstration projects in their compliance with human subjects research protection set forth in the Code of Federal Regulations.[84] This will include review of the demonstration projects' required plans to safeguard study participants' privacy and confidentiality and their documentation of procedures for electronic and physical protection of project participant information and data, in accordance with HIPAA regulations and human subjects research protections. Any deficits identified must be remedied with the assistance of the ETAC.

e. Institutional Review Boards. The ETAC is also expected to serve as a resource for demonstration projects regarding the Institutional Review Board review, approval and renewals of client-level data collection instruments, informed consents and any other pertinent evaluation documentation. Both the ETAC and the demonstration projects will be required to submit documentation to the SPNS program of all IRB approvals and annual renewals.

f. Intervention Manuals. The ETAC will also assist each demonstration project in the development of their required Intervention Manual, which will document the methodology, implementation and outcomes of their intervention project, in order to guide its potential replication in the future.

The ETAC will be expected to conduct an annual site visit with each demonstration project throughout the initiative with SPNS program staff. The ETAC will develop a Site Visit Protocol in Year 1 to include all potential TA needs to be assessed, evaluated and met during site visits. TA needs during the early years of the initiative will likely focus on implementing the interventions, local evaluations and the multi-site evaluations, while in the later years TA will address issues of data quality. Due to these initiative dynamics, the Site Visit Protocol will require revision in each succeeding year of the initiative. Site Visit Protocols should address TA needs across the domains mentioned above, and may include the capacity building needs listed below.

2) Serve as a Capacity Building Resource

The ETAC will be responsible for conducting capacity building activities for the demonstration projects as appropriate that relate to the provision of quality clinical and culturally competent HIV primary care to transgender women of color. It should be noted that Ryan White medical providers are already expected to be or become familiar with medical management issues unique to HIV-positive transgender people under their care, including hormonal therapy. Clinical and social service staff also are expected to be respectful, supportive and familiar with LGBT cultures in order to create a welcoming environment, and be aware of community agencies with additional resources to serve sexual and gender minorities.[85]

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[84] See Code of Federal Regulations, Title 45, Part 46 Protection of Human Subjects, Revised January 15, 2009 Effective July 14, 2009. Available from: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html
[85] Health Resources and Services Administration. *Guide for HIV/AIDS Clinical Care*, Supporting Patients in Care. U.S. Department of Health and Human Services, Health Resources and Services Administration, HIV/AIDS Bureau, January 2011. Available online at: http://hab.hrsa.gov/deliverhivaidscare/clinicalguide11/

However, as noted previously the need remains for much improvement in providing services that are both culturally and clinically competent to this marginalized population. Fear of providers leads many transgender people to avoid the healthcare system, indicating the need for improvements in provider sensitivity and awareness, patient-provider communications, and patient education. Transgender health clinical practices vary greatly, and best practices and clinical standards are yet to be evaluated and disseminated widely.

Transgender women of color also encounter the same culturally-specific racial and ethnic barriers as their non-transgender peers. The successful applicant will describe in detail its approach to the provision of culturally and linguistically competent health care and social services to transgender people of color. The approach should build upon the *National Standards for Culturally and Linguistically Appropriate Services* developed by the Office of Minority Health, Department of Health and Human Services.[86]

The ETAC will be tasked with building capacity in the clinical care of transgender women of color through didactic and case study presentations for demonstration project staff. The ETAC will also distribute topical information to clinical staff of demonstration projects though email, conference calls, webinars, and through its website to enhance communal learning and quality improvement. Other capacity building activities may include transgender health services; transgender-sensitive mental health and substance abuse treatment; development or enhancement of referral networks to ensure a continuum of community-based care; means to ensure continuous access to medications (including ADAP eligibility and enrollment); development of patient education materials; and methods to address the housing, vocational, social, emotional, mental, spiritual and safety needs of transgender women of color.

3) Conduct a Rigorous Multi-Site Evaluation

The successful applicant, in collaboration with SPNS staff, will design and implement a comprehensive national multi-site evaluation plan to assess the effectiveness of the demonstration project interventions in improving timely entry, engagement and retention of transgender women of color in quality HIV primary care. The ETAC's proposed staff should have demonstrated knowledge and expertise in conducting health care evaluations among HIV infected populations and in transgender health. As terms of their award, demonstration projects must agree to fully cooperate with the ETAC in the multi-site evaluation, and to include at a minimum, a 0.25 full-time equivalent (FTE) local evaluator in their project staff. The ETAC will work closely with the Principal Investigator/Project Director and local evaluator of each demonstration project and SPNS staff to implement the multi-site evaluation plan. The multi-site evaluation will collect and report relevant quantitative and qualitative outcome, process and cost measures for the interventions, and also assess the treatment experience of the multi-site participant cohort as a whole.

Outcome measures may include but are not limited to client characteristics; biomedical and behavioral health indicators; barriers to access and factors facilitating the utilization of core HIV

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[86] See *National Standards for Culturally and Linguistically Appropriate Services* at: http://minorityhealth.hhs.gov/templates/browse.aspx?lvl=2&lvlID=15

medical and support services; medication adherence and HAART-hormone interactions; and other outcome measures proposed by the ETAC. The *Process Evaluation* will document any barriers to the effective implementation of strategies employed by the interventions. A *Cost Analysis Study* (or cost effectiveness study, if feasible) will document the labor and programmatic costs incurred by each intervention, to inform its potential future replication. Costs relating to the evaluation of this initiative will not be included in the cost study. In the spring of 2012, the Office of HIV/AIDS Policy (OHAP) of the Department of Health and Human Services will issue guidance requiring use of a standard set of metrics to assure consistent outcome evaluation for the National HIV/AIDS Strategy. To assure expeditious translation of research into practice, both the ETAC and the demonstration sites will be required to incorporate these data standards where appropriate in planning their multi-site and local evaluations for the initiative.

The successful applicant will describe its detailed multi-site evaluation plan and provide a sound theoretical basis for its proposed multi-site evaluation methodology. Because this population is under-studied, the ETAC may also propose additional focused studies regarding related aspects of HIV testing and treatment, transgender health and access to substance abuse treatment, mental health services, transgender health services and routine health care. Examples of these focused studies include but are not limited to case studies; provider-patient communications and provider cultural competencies; clinical care competencies with regard to transgender health; secondary prevention of HIV transmission; social support and patient education needs. These focused studies will be developed in collaboration with the demonstration projects and the SPNS program.

The successful applicant will be required to submit its proposed multi-site evaluation plan and any other related studies to its Institutional Review Board (IRB) for review and approval. The ETAC will be required to submit their IRB's approval and annual renewals for all client-level data collection instruments, informed consents and evaluation materials to the SPNS program. The ETAC also will be responsible for tracking the demonstration projects' required submissions of their IRB approvals and annual renewals for the multi-site evaluation, their local evaluation and any other related studies.

The ETAC will coordinate the efforts of demonstration projects to assure the privacy and confidentiality of study participants' and their health-seeking efforts. The ETAC and the demonstration projects will be expected to conform with regulations for human subjects research protection as set forth in the Code of Federal Regulations.[87] All key ETAC project personnel are expected to have taken Human Subjects Research Protections training, such as the online training offered by the National Institutes of Health (NIH) online. [88] The ETAC will be expected to review the required plans of demonstration projects to safeguard the privacy and confidentiality of study participants, in accordance with HIPAA regulations and human subjects research protections.

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[87] See Code of Federal Regulations, Title 45, Part 46 Protection of Human Subjects, Revised January 15, 2009 Effective July 14, 2009. Available from: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html
[88] See http://phrp.nihtraining.com/users/login.php

The successful applicant will be expected to construct and maintain a secure website for the initiative to serve as a data portal for the reporting of multi-site evaluation data by the demonstration projects. Applicants must demonstrate they have documented procedures for the electronic and physical protection of participant information and data. The website should serve as a communications nexus for the initiative, and have both public access for promotion of the initiative and private password-protected access for demonstration project, ETAC and SPNS staff. In addition to the secure data entry portal, the website will be expected to support technical assistance resources for the multi-site evaluation; ongoing documentation of presentation, publication and dissemination efforts for the initiative; a calendar of upcoming initiative events and national conferences with abstract submission deadlines; a registration system for the twice-a-year national meetings of the initiative; recent findings of interest from outside the initiative; and links for relevant resources. Demonstration projects will be expected to contribute materials for inclusion on the initiative's website.

4) Lead and Coordinate Publication and Dissemination of Findings and Lessons Learned

The ETAC will be expected to lead the publication and dissemination activities for the initiative, working in collaboration with the demonstration projects and SPNS staff. The ETAC will form a publications and disseminations committee, with SPNS staff and demonstration projects expected to contribute at least one staff member to this committee. The publications and disseminations committee will work collaboratively to formulate its own publication and policy guidelines to cover such issues as governance and function; authorship; multi-site data requests; and other operational issues. The publications and disseminations committee will be expected to generate research questions; topics for presentations and publications; concept sheets and analyses; and an overall dissemination plan for the initiatives products.

The successful applicant will have personnel with the necessary skills and experience to communicate project findings and lessons learned to local communities, state and national conferences, and policymakers, and to lead collaborative efforts in the writing and publishing of findings in peer reviewed journals and in making presentations at conferences. Project findings to be disseminated include, but are not limited to, innovative strategies and novel approaches to improve the identification of transgender women of color living with HIV infection; their timely entry, engagement and retention in high quality HIV primary care; interactions between HAART medications and hormonal therapy; and lessons learned and best practices in transgender health.

The successful applicant will be expected to lead and coordinate the logistics for two national meetings in each of the five years of the initiative with the demonstration projects. This activity includes but is not limited to site location and logistics; meeting registration; and the development of meeting agendas and presentation in collaboration with SPNS and demonstration project staff. All SPNS grantee meetings will take place in the Washington, DC metropolitan area, and the ETAC should allocate funds for the Principal Investigator, Project Director, and two other key staff members to attend these 2 day meetings.

2. Summary of Funding

This program will provide funding during federal fiscal years 2012 -2016. Approximately

$550,000 is expected to be available annually to fund one (1) awardee. Applicants may apply for a ceiling amount of up to $550,000 per year. The project period is five (5) years. Funding beyond the first year is dependent on the availability of appropriated funds for the SPNS Program in subsequent fiscal years, awardee satisfactory performance, and a decision that continued funding is in the best interest of the Federal Government.

III. Eligibility Information

1. Eligible Applicants

Eligible applicants include public and nonprofit entities, including faith-based and community-based organizations, institutions of higher education; and nonprofits having a 501 (c)(3) status with IRS other than institutions of higher education. Please note that applicants for this funding opportunity announcement may not apply for funding under the Demonstration Site announcement (HRSA-12-099).

2. Cost Sharing/Matching

Cost Sharing/Matching is not required for this program.

3. Other

Applications that exceed the ceiling amount of $550,000 will be considered non-responsive and will not be considered for funding under this announcement.

Any application that fails to satisfy the deadline requirements referenced in *Section IV.3* will be considered non-responsive and will not be considered for funding under this announcement.

IV. Application and Submission Information

1. Address to Request Application Package

Application Materials and Required Electronic Submission Information
HRSA *requires* applicants for this funding opportunity announcement to apply electronically through Grants.gov. This robust registration and application process protects applicants against fraud and ensures that only authorized representatives from an organization can submit an application. Applicants are responsible for maintaining these registrations, which should be completed well in advance of submitting your application. All applicants *must* submit in this manner unless they obtain a written exemption from this requirement in advance by the Director of HRSA's Division of Grants Policy. Applicants must request an exemption in writing from **DGPWaivers@hrsa.gov**, and provide details as to why they are technologically unable to submit electronically through the Grants.gov portal. Your email must include the HRSA announcement number for which you are seeking relief, the organization's DUNS number, the name, address, and telephone number of the organization and the name and telephone number of

the Project Director as well as the Grants.gov Tracking Number (GRANTXXXX) assigned to your submission along with a copy of the "Rejected with Errors" notification you received from Grants.gov. **HRSA and its Digital Services Operation (DSO) will only accept paper applications from applicants that received prior written approval.** However, the application must still be submitted by the deadline. Suggestion: submit application to Grants.gov at least two days before the deadline to allow for any unforeseen circumstances.

Note: Central Contractor Registration (CCR) information must be updated at least every 12 months to remain active (for both grantees and sub-recipients). As of August 9, 2011, Grants.gov began rejecting submissions from applicants with expired CCR registrations. Although active CCR registration at time of submission is not a new requirement, this systematic enforcement will likely catch some applicants off guard. According to the CCR Website it can take 24 hours or more for updates to take effect, so ***check for active registration well before your grant deadline.***

An applicant can view their CCR Registration Status by visiting http://www.bpn.gov/CCRSearch/Search.aspx and searching by their organization's DUNS. The CCR Website provides user guides, renewal screen shots, FAQs and other resources you may find helpful.

Applicants that fail to allow ample time to complete registration with CCR and/or Grants.gov will not be eligible for a deadline extension or waiver of the electronic submission requirement.

All applicants are responsible for reading the instructions included in HRSA's *Electronic Submission User Guide,* available online at http://www.hrsa.gov/grants/apply/userguide.pdf. This Guide includes detailed application and submission instructions for both Grants.gov and HRSA's Electronic Handbooks. Pay particular attention to Sections 2 and 5 that provide detailed information on the competitive application and submission process.

Applicants are also responsible for reading the Grants.gov Applicant User Guide, available online at http://www.grants.gov/assets/ApplicantUserGuide.pdf. This Guide includes detailed information about using the Grants.gov system and contains helpful hints for successful submission.

Applicants must submit proposals according to the instructions in the Guide and in this funding opportunity announcement in conjunction with Application Form SF-424. The forms contain additional general information and instructions for applications, proposal narratives, and budgets. The forms and instructions may be obtained by:

1) Downloading from http://www.grants.gov, or

2) Contacting the HRSA Digital Services Operation (DSO) at:
    HRSADSO@hrsa.gov

Each funding opportunity contains a unique set of forms and only the specific forms package posted with an opportunity will be accepted for that opportunity. Specific instructions for

preparing portions of the application that must accompany Application Form SF-424 appear in the "Application Format Requirements" section below.

2. Content and Form of Application Submission

Application Format Requirements
The total size of all uploaded files may not exceed the equivalent of 80 pages when printed by HRSA. The total file size may not exceed 10 MB. The 80-page limit includes the abstract, project and budget narratives, attachments, and letters of commitment and support. Standard forms are NOT included in the page limit. **We strongly urge you to print your application to ensure it does not exceed the 80-page limit. Do not reduce the size of the fonts or margins to save space. See the formatting instructions in Section 5 of the Electronic Submission User Guide referenced above.**

Applications must be complete, within the 80-page limit, within the 10 MB limit, and submitted prior to the deadline to be considered under this announcement.

Application Format
Applications for funding must consist of the following documents in the following order:

SF-424 Non-Construction – Table of Contents

> ☙ It is mandatory to follow the instructions provided in this section to ensure that your application can be printed efficiently and consistently for review.
> ☙ Failure to follow the instructions may make your application non-responsive. Non-responsive applications will not be considered under this funding opportunity announcement.
> ☙ For electronic submissions, applicants only have to number the electronic attachment pages sequentially, resetting the numbering for each attachment, i.e., start at page 1 for each attachment. Do not attempt to number standard OMB approved form pages.
> ☙ For electronic submissions, no Table of Contents is required for the entire application. HRSA will construct an electronic table of contents in the order specified.

Application Section	Form Type	Instruction	HRSA/Program Guidelines
Application for Federal Assistance (SF-424)	Form	Pages 1, 2 & 3 of the SF-424 face page.	Not counted in the page limit
Project Summary/Abstract	Attachment	Can be uploaded on page 2 of SF-424 - Box 15	Required attachment. Counted in the page limit. Refer to the funding opportunity announcement for detailed instructions.
Additional Congressional District	Attachment	Can be uploaded on page 3 of SF-424 - Box 16	As applicable to HRSA; not counted in the page limit.
Project Narrative Attachment Form	Form	Supports the upload of Project Narrative document	Not counted in the page limit.
Project Narrative	Attachment	Can be uploaded in Project Narrative Attachment form.	Required attachment. Counted in the page limit. Refer to the funding opportunity announcement for detailed instructions. Provide table of contents specific to this document only as the first page.
SF-424A Budget Information - Non-Construction Programs	Form	Pages 1-2 to support structured budget for the request of Non-construction related funds.	Not counted in the page limit.
Budget Narrative Attachment Form	Form	Supports the upload of Project Narrative document.	Not counted in the page limit.
Budget Narrative	Attachment	Can be uploaded in Budget Narrative Attachment form.	Required attachment. Counted in the page limit. Refer to the funding opportunity announcement for detailed instructions.
SF-424B Assurances - Non-Construction Programs	Form	Supports assurances for non-construction programs.	Not counted in the page limit.
Project/Performance Site Location(s)	Form	Supports primary and 29 additional sites in structured form.	Not counted in the page limit.
Additional Performance Site Location(s)	Attachment	Can be uploaded in the SF-424 Performance Site Location(s) form. Single document with all additional site location(s)	Not counted in the page limit.

Application Section	Form Type	Instruction	HRSA/Program Guidelines
Disclosure of Lobbying Activities (SF-LLL)	Form	Supports structured data for lobbying activities.	Not counted in the page limit.
Other Attachments Form	Form	Supports up to 15 numbered attachments. This form only contains the attachment list.	Not counted in the page limit.
Attachment 1-15	Attachment	Can be uploaded in Other Attachments form 1-15.	Refer to the attachment table provided below for **specific** sequence. Counted in the page limit.

- To ensure that attachments are organized and printed in a consistent manner, follow the order provided below. Note that these instructions may vary across programs.
- Evidence of Non-Profit status and invention related documents, if applicable, must be provided in the other attachment form.
- Additional supporting documents, if applicable, can be provided using the available rows. Do not use the rows assigned to a specific purpose in the program funding opportunity announcement.
- Merge similar documents into a single document. Where several documents are expected in the attachment, ensure that you place a table of contents cover page specific to the attachment. The Table of Contents page will not be counted in the page limit.
- Limit the file attachment name to under 50 characters. Do not use any special characters (e.g., %, /, #) or spacing in the file name or word separation. (The exception is the underscore (_) character.) Your attachment will be rejected by Grants.gov if you use special characters or attachment names greater than 50 characters.

Attachment Number	Attachment Description (Program Guidelines)
Attachment 1	Copy of SF-424A Section B for Fifth Year Budget
Attachment 2	Line Item Budgets for Years 1 through 5 Spreadsheet Table
Attachment 3	Staffing Plan
Attachment 4	Position Descriptions
Attachment 5	Biosketches
Attachment 6	Work Plan
Attachment 7	Project organizational chart
Attachment 8	Signed letters of support and memoranda of agreement, and descriptions of proposed and existing contracts
Attachment 9	Cultural and Linguistic Factors Competency Statement
Attachment 10	Healthy People 2020 Statement
Attachment 11	Other Relevant Documents

Application Format

i. *Application Face Page*
Complete Application Form SF-424 provided with the application package. Prepare
according to instructions provided in the form itself. Important note: enter the name of the
Project Director in 8. f. "Name and contact information of person to be contacted on matters
involving this application." If, for any reason, the Project Director will be out of the office,
please ensure their email Out of Office Assistant is set so HRSA will be aware if any issues
arise with the application and a timely response is required. For information pertaining to the
Catalog of Federal Domestic Assistance, the CFDA Number is 93.928.

DUNS Number
All applicant organizations (and subrecipients of HRSA award funds) are required to have a
Data Universal Numbering System (DUNS) number in order to apply for a grant or
cooperative agreement from the Federal Government. The DUNS number is a unique nine-
character identification number provided by the commercial company, Dun and Bradstreet.
There is no charge to obtain a DUNS number. Information about obtaining a DUNS number
can be found at http://fedgov.dnb.com/webform or call 1-866-705-5711. Please include the
DUNS number in item 8c on the application face page on the application face page.
Applications *will not* be reviewed without a DUNS number. Note: A missing or incorrect
DUNS number is the number one reason for applications being "Rejected for Errors" by
Grants.gov. HRSA will not extend the deadline for applications with a missing or incorrect
DUNS. Applicants should take care in entering the DUNS number in the application.

Additionally, the applicant organization (and any subrecipient of HRSA award funds) is
required to register annually with the Federal Government's Central Contractor Registry
(CCR) in order to do electronic business with the Federal Government. CCR registration
must be maintained with current, accurate information at all times during which an entity has
an active award or an application or plan under consideration by HRSA. It is extremely
important to verify that your CCR registration is active and your Marketing Partner ID
Number (MPIN) is current. Information about registering with the CCR can be found at
http://www.ccr.gov.

ii. *Table of Contents*
The application should be presented in the order of the Table of Contents provided earlier.
Again, for electronic applications no table of contents is necessary as it will be generated by
the system. (Note: the Table of Contents will not be counted in the page limit.)

iii. *Budget*
Complete Application Form SF-424A Budget Information – Non-Construction Programs
provided with the application package. Please complete Sections A, B, E, and F. For Section
B, complete columns (1) though (4) for each of the first four years of the project. For year 5,
complete and submit a copy of Section B of the SF-424A as **Attachment 1**.

Applicants also must submit line item budgets **for each year of the proposed project period**
as a spreadsheet table, using the Section B Budget Categories of the SF-424A and breaking
down sub-categorical costs. Under Personnel, please list each position by title and name, with
annual salary, FTE, and salary charged to the grant <u>and</u> provided in-kind. Equipment,
supplies (office and medical) and contractual should each have individual items listed

separately. The categorical amounts requested on the SF424A and listed on the line-item budget spreadsheet tables must match. The budget must relate to the activities proposed in the Project Narrative and the Work Plan. These line item budgets for Years 1 through 5 should be included in a single spreadsheet table as **Attachment 2**.

Salary Limitation:
The Consolidated Appropriations Act, 2012 (P.L. 112-74) enacted December 23, 2011, limits the salary amount that may be awarded and charged to HRSA grants and cooperative agreements. Award funds may not be used to pay the salary of an individual at a rate in excess of Executive Level II. The Executive Level II salary of the Federal Executive Pay scale is $179,700. This amount reflects an individual's base salary <u>exclusive</u> of fringe and any income that an individual may be permitted to earn outside of the duties to the applicant organization. This salary limitation also applies to subawards/subcontracts under a HRSA grant or cooperative agreement.

As an example of the application of this limitation: If an individual's base salary is $350,000 per year plus fringe benefits of 25% ($87,500) and that individual is devoting 50% of their time to this award, their base salary should be adjusted to $179,700 plus fringe of 25% ($44,925) and a total of $112,312.50 may be included in the project budget and charged to the award in salary/fringe benefits for that individual. See the breakdown below:

Individual's *actual* base full time salary: $350,000 50% of time will be devoted to project	
Direct salary	$175,000
Fringe (25% of salary)	$43,750
Total	$218,750
Amount that may be claimed on the application budget due to the legislative salary limitation: Individual's base full time salary *adjusted* to Executive Level II: $179,700 50% of time will be devoted to the project	
Direct salary	**$89,850**
Fringe (25% of salary)	**$22,462.50**
Total amount	**$112,312.50**

iv. *Budget Justification*
Provide a narrative that explains the amounts requested for each line in the budget. The budget justification should specifically describe how each item will support the achievement of proposed objectives. The budget period is for ONE year. However, the applicant **must** submit one-year budgets for each of the subsequent budget periods within the requested project period (five years) at the time of application. Line item information must be provided to explain the costs entered in the SF-424A. Be very careful about showing how each item in the "other" category is justified. For subsequent budget years, the justification narrative should highlight the changes from year one or clearly indicate that there are no substantive budget changes during the project period. The budget justification MUST be concise. Do NOT use the justification to expand the project narrative.

Budget for Multi-Year Award
This announcement is inviting applications for project periods of up to five (5) years. Awards, on a competitive basis, will be for a one-year budget period; although the project period may be for up to five (5) years. Submission and HRSA approval of your Progress Report(s) and any other required submission or reports is the basis for the budget period renewal and release of subsequent year funds. Funding beyond the one-year budget period but within the five-year project period is subject to availability of funds, satisfactory progress of the awardee, and a determination that continued funding would be in the best interest of the Federal Government.

Include the following in the Budget Justification Narrative:

Personnel Costs: Personnel costs should be explained by listing each staff member who will be supported from funds, name (if possible), position title, percentage of full-time equivalency, and annual salary. In-kind personnel contributions, including percentage of full-time equivalency, should also be listed. Reminder: Award funds may not be used to pay the salary of an individual at a rate in excess of Executive Level II or $179,700. An individual's base salary, per se, is NOT constrained by the legislative provision for a limitation of salary. The rate limitation simply limits the amount that may be awarded and charged to HRSA grants and cooperative agreements. Please provide an individual's actual base salary if it exceeds the cap. See the sample below.

Sample:

Name	Position Title	% of FTE	Annual Salary	Amount Requested
J. Smith	Chief Executive Officer	50	$179,700*	$89,850
R. Doe	Nurse Practitioner	100	$75,950	$75,950
D. Jones	Data/AP Specialist	25	$33,000	$8,250

*Actual annual salary = $350,000

Fringe Benefits: List the components that comprise the fringe benefit rate, for example health insurance, taxes, unemployment insurance, life insurance, retirement plans, and tuition reimbursement. The fringe benefits should be directly proportional to that portion of personnel costs that are allocated for the project. If an individual's base salary exceeds the legislative salary cap, please adjust fringe accordingly.

Travel: List travel costs according to local and long distance travel. For local travel, the mileage rate, number of miles, reason for travel and staff member/consumers completing the travel should be outlined. Long distance travel for staff members to attend the two SPNS grantee meetings held each project year in Washington, DC should be broken down by airfare/train fare, ground transportation, lodging and meals and incidental expenses. The budget should also reflect the travel expenses associated with participating in meetings and other proposed trainings or workshops.

Equipment: List equipment costs and provide justification for the need of the equipment to carry out the program's goals. Extensive justification and a detailed status of current equipment must be provided when requesting funds for the purchase of computers and furniture items that meet the definition of equipment (a unit cost of $5,000 or more and a useful life of one or more years). Please note that most computer devices and digital

accessories generally do not meet the Federal equipment definition ($5,000 or more per unit), and therefore those costs should be listed in the Supplies category.

Supplies: List the items that the project will use. In this category, separate office supplies from medical and educational purchases. Office supplies could include computers and peripherals that do not meet the definition of equipment, paper, pencils, and the like. Medical supplies are syringes, blood tubes, plastic gloves, etc., and educational supplies may be pamphlets and educational videotapes. Remember, they must be listed separately.

Contractual: Applicants are responsible for ensuring that their organization or institution has in place an established and adequate procurement system with fully developed written procedures for awarding and monitoring all contracts. Applicants must provide a clear explanation as to the purpose of each contract, how the costs were estimated, and the specific contract deliverables. Reminder: recipients must notify potential subrecipients that entities receiving subawards must be registered in the CCR and provide the recipient with their DUNS number.

Other: Put all costs that do not fit into any other category into this category and provide an explanation of each cost in this category. In some cases, rent, utilities and insurance fall under this category if they are not included in an approved indirect cost rate.

Applicants may include the cost of access accommodations as part of their project's budget, including sign interpreters, plain language and health literate print materials in alternate formats (including Braille, large print, etc.); and cultural/linguistic competence modifications such as use of cultural brokers, translation or interpretation services at meetings, clinical encounters, and conferences, etc.

Indirect Costs: Indirect costs are those costs incurred for common or joint objectives which cannot be readily identified but are necessary to the operations of the organization, e.g., the cost of operating and maintaining facilities, depreciation, and administrative salaries. For institutions subject to OMB Circular A-21, the term "facilities and administration" is used to denote indirect costs. If an organization applying for an assistance award does not have an indirect cost rate, the applicant may wish to obtain one through HHS's Division of Cost Allocation (DCA). Visit DCA's website at: http://rates.psc.gov/ to learn more about rate agreements, the process for applying for them, and the regional offices which negotiate them.

v. *Staffing Plan and Personnel Requirements*

Applicants must present a staffing plan as **Attachment 3.** The Staffing plan should include education and professional qualifications for each key staff position. The staffing plan also should include a justification for the amount of time requested for each staff position. Key staff are defined as those with direct responsibility for ETAC activities, and at a minimum, include the Principal Investigator, Project Director, and a lead clinician. Other staff may include site liaisons responsible for providing technical assistance and capacity building to the demonstration projects; and evaluation, data collection and website development and support. If applicable, the staffing plan should include consultants; staff within subcontracted organizations; and staff within agencies providing significant in-kind support through memoranda of agreement or letters of support.

Include position descriptions for the roles, responsibilities, and qualifications required of proposed project staff as **Attachment 4**. Include biographical sketches for any key employed personnel that will be assigned to work on the proposed project as **Attachment 5**.

vi. *Assurances*

Complete Application Form SF-424B Assurances – Non-Construction Programs provided with the application package.

vii. *Certifications*

Use the Certifications and Disclosure of Lobbying Activities Application Form provided with the application package.

viii. *Project Abstract*

Provide a summary of the application. Because the abstract is often distributed to provide information to the public and Congress, please prepare this so that it is clear, accurate, concise, and without reference to other parts of the application. It must include a brief description of the proposed project including its goals; the target populations to be served; the needs to be addressed; a summary of the proposed multi-site evaluation; and a summary of proposed plan of project operation. The project abstract must be single-spaced and limited to one page in length. Please place the following at the top of the abstract:

- *Project Title*
- *Applicant Organization Name*
- *Address*
- *Project Director Name*
- *Contact Name and Phone Numbers (Voice, Fax)*
- *E-Mail Address*
- *Web Site Address, if applicable*

ix. *Project Narrative*

This section provides a comprehensive framework and description of all aspects of the proposed program. It should be succinct, self-explanatory and well organized so that reviewers can understand the proposed project.

Use the following section headers for the Narrative:

- *INTRODUCTION*
  Provide a clear and succinct description of the roles and activities of the Evaluation and Technical Assistance Center (ETAC). Specifically, how the ETAC will provide leadership in the multi-site evaluation and dissemination of findings, and technical assistance and capacity building to the demonstration projects of the SPNS *Enhancing Engagement and Retention in Quality HIV Care for Transgender Women of Color* initiative. Briefly describe the multi-site evaluation, technical assistance and capacity building services that the ETAC will provide. Briefly describe the applicant organization and any collaborating organizations.

- *NEEDS ASSESSMENT*
  Provide a summary of the literature that demonstrates a comprehensive understanding of

the issues that interfere with identifying transgender women of color living with HIV infection, and engaging and retaining them in quality HIV primary care. Discuss the factors driving incidence and prevalence rates of HIV infection among transgender women of color, using the most recent, available, *transgender*-specific data (i.e., non-MSM). Data sources may include HIV testing data; surveillance and epidemiology reports and profiles of state and local public health departments; needs assessment surveys; risk behavioral surveys; programmatic data and other transgender-specific studies. Discuss HIV counseling and testing for this population, with a focus on challenges in identifying those who are at high risk of HIV infection or are infected with HIV but are unaware of their HIV status; are aware of their HIV infection but have never been engaged to care; are aware but have refused referral to care; or have dropped out of care. Propose strategies that may be employed to overcome these challenges.

Describe the issues that interfere with engaging and retaining transgender women of color living with HIV infection in quality HIV primary care, including those who are newly diagnosed during the project, and what strategies may be used to overcome them. Provide a summary of the policy, financial, structural, cultural and clinical issues related to improving timely entry, access to and retention in quality HIV care for transgender women of color.

- *METHODOLOGY*
  Describe a plan for the provision of technical assistance (TA) to the demonstration projects over the course of the initiative, to include a routine means of TA needs assessment. Describe what kinds of TA needs are anticipated, and by what means they will be addressed, across the following domains: program development, implementation and sustainability; clinical consultation; multi-site and local evaluations; human research subjects protection; Institutional Review Board approval and renewal; and intervention manuals. Describe a plan for review of the demonstration projects' plans to safeguard the privacy and confidentiality of study participants and their documented procedures for the electronic and physical protection of study participant information and data, and a means of addressing deficits. Describe the elements of a site visit protocol for the annual site visits to the demonstration projects.

  Describe a plan for providing capacity building relating to the provision of quality clinical and culturally competent HIV primary care and social services to transgender women of color. The plan should include the scope and delivery methods of the capacity building activities, identifying areas where improvements are needed in clinical care and ancillary service delivery based upon the research literature, as well as methods proposed to address deficits. Describe in detail your approach to the provision of culturally and linguistically competent health care and social services to transgender people of color, with a focus on racial, ethnic, sexual and gender minority disparities faced by this population.

  Describe a plan for a rigorous national multi-site evaluation across demonstration projects that will have maximum impact on practice and policy affecting timely entry, access to and retention in quality HIV primary care for transgender women of color. Discuss anticipated evaluation questions for assessing the effectiveness of demonstration project interventions. Describe the methodology that will be used to conduct the multi-site evaluation and provide the rationale for its selection. Outline the outcome, process and cost elements of the multi-site evaluation, and propose possible measures for them. Propose any additional

focused studies of interest relating to transgender women of color, describing their rationale and possible impact.

Describe your approach in leading publication and dissemination efforts for the initiative's findings and lessons learned. Provide a brief discussion of how a publications and disseminations committee would operate. Describe the experience of proposed key project staff (including any consultants and subcontractors) in collaborative writing and publishing study findings in peer reviewed journals. Provide a dissemination plan identifying appropriate venues and target audiences, including but not limited to policy makers and national conferences geared toward HIV primary care and social service providers. The dissemination plan should include lessons learned or best practices and help facilitate the replication of interventions proven effective by the multi-site and local evaluations by HIV primary care and social service organizations serving transgender women of color at risk or living with HIV infection. Describe the experience of proposed key project staff in making presentations to local communities, state and national conferences and to policy makers.

- *WORK PLAN*
  Provide a work plan that delineates the ETAC's goals for the five-year project period. The work plan should directly relate to your Methodology section and the program requirements of this announcement. Include all aspects of planning and provision of technical assistance and capacity building; design and implementation of the multi-site evaluation; and publication and dissemination activities. The work plan should include clearly written (1) goals; (2) objectives that are specific, time-framed, and measurable; (3) action steps; (4) staff responsible for each action step (including consultants); and (5) anticipated dates of completion. Please note that goals for the work plan are to be written for the entire proposed five year project period, but objectives and action steps are required only for the goals set for Year 1. Include the project's work plan as **Attachment 6**.

- *RESOLUTION OF CHALLENGES*
  Discuss the challenges that are likely to be encountered in planning and implementing the activities described in the work plan, and describe realistic and appropriate approaches that will be used to resolve the challenges.

- *EVALUATION AND TECHNICAL ASSISTANCE CAPACITY*
  Describe your expertise in engagement and retention in HIV treatment and in transgender clinical health. Describe your capacity to conduct a comprehensive multi-site evaluation to assess the interventions of the demonstration projects and the multi-site participant cohort as a whole. Include evidence of experience, skills, training and knowledge of proposed key project staff (including any consultants and subcontractors) in achieving scientific excellence and evaluation integrity in conducting a multi-site evaluation of national scope that will have maximum impact on practice and policy affecting timely entry, access to and retention in quality HIV primary care for transgender women of color.

  Describe how the proposed key project staff (including any consultants and subcontractors, if applicable) have the necessary knowledge, experience, training and skills in designing and implementing public health program evaluations, specifically quantitative and qualitative outcome and process evaluations and cost studies of innovative HIV access and retention projects. Include any specific experience in the evaluation of programs reaching those who are unaware of their HIV status, as well as engaging and retaining those newly

diagnosed in quality HIV primary care. Include any specific experience in the design, implementation and evaluation of programs serving transgender women of color at risk or living with HIV infection. Describe any experience in conducting focused studies related to engagement and retention in HIV treatment and transgender health, and if applicable, describe any published materials and presentations.

Describe the capacity of the proposed project staff to provide leadership and technical assistance to demonstration sites for the multi-site and local evaluations. Describe the experience of proposed project staff (to include consultants' and subcontractors', if applicable) in providing technical assistance to HIV primary care and social service organizations; providing capacity building to HIV primary care and social service organizations; and logistical planning, implementation and evaluation of national meetings. Describe any expertise in transgender health, with a focus on clinical consultation and cultural competencies. Describe your approach to working collaboratively with the demonstration projects in leading data collection and reporting efforts for the multi-site evaluation and additional focused evaluation studies.

State your agreement to submit to the SPNS program on an annual basis proof of IRB approvals and renewals for all client-level data collection instruments, informed consents and evaluation materials. Describe any training in human subjects research protection by proposed project staff. Describe your plans to safeguard the privacy and confidentiality of study participants, in accordance with HIPAA regulations and human subjects research protections. Describe your plans for the initiative's website, its data portal and your documented procedures for the electronic and physical protection of participant information and data. Describe your system of tracking and reporting to SPNS staff the demonstration projects' IRB approvals and annual renewals for the multi-site evaluation, their local evaluations and any other related studies.

- *ORGANIZATIONAL INFORMATION*
  Describe the organization's mission, organizational structure, the quality and availability of facilities and personnel, and the scope of current activities of the organization. Describe how these all contribute to the organization's ability to successfully carry out a project of this magnitude and meet the goals and objectives of the initiative. Describe your organization's capacity to conduct the required multi-site evaluation, technical assistance, and capacity building activities described earlier in this announcement. Describe the capacity of your organization's management information systems to support a comprehensive multi-site evaluation in the collection, reporting and secure storage of client-level data.

  Include a one-page project organizational chart depicting the organizational structure of only the project, not the entire organization, and include subcontractors and other significant collaborators, as **Attachment 7**. If consultants and/or subcontractors will be used to carry out aspects of the proposed project, describe their roles and responsibilities. Current and proposed collaborating organizations and individuals must demonstrate their commitment to fulfill the goals and objectives of the project through signed and dated letters or memoranda of agreement/understanding. If applicable, include any signed and dated letters of support or memoranda of agreement or understanding, and descriptions of any existing or proposed contracts relating to the proposed project, as **Attachment 8**.

Describe your cultural competency capabilities. *Cultural competence* means having a set of congruent behaviors, attitudes, and policies that come together in a system or organization or among professionals that enables effective work in cross-cultural situations.[89] It includes an understanding of integrated patterns of human behavior, including language, beliefs, norms, and values, as well as socioeconomic and political factors that may have significant impact on psychological well-being and incorporating those variables into assessment and treatment. Include the project's cultural and linguistic competence factors in **Attachment 9.**

ADDITIONAL NARRATIVE GUIDANCE

Instructions: In order to ensure that the Review Criteria in this Funding Opportunity Announcement Template are fully addressed, this table provides a bridge between the narrative language and where each section falls within the review criteria.

Narrative Section	**Generic Review Criteria**
Introduction	(1) Need
Needs Assessment	(1) Need
Methodology	(2) Response (3) Evaluative Measures & (4) Impact
Work Plan	(2) Response & (4) Impact
Resolution of Challenges	(2) Response
Evaluation and Technical Assistance Capacity	(5) Resources/Capabilities
Organizational Information	(5) Resources/Capabilities
(Budget and Budget Justification)	(6) Support Requested – the budget section should include sufficient justification to allow reviewers to determine the reasonableness of the support requested.

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x. *Attachments*
Please provide the following items to complete the content of the application. Please note that these are supplementary in nature, and are not intended to be a continuation of the project narrative. Unless otherwise noted, attachments count toward the application page limit. **Each attachment must be clearly labeled**.

Attachment 1: *Copy of SF-424A Section B for Fifth Year Budget*
For the proposed year 5 budget, complete and submit a copy of Section B of the SF-424A.

Attachment 2: *Line Item Budgets Spreadsheet for Years 1 through 5*
Submit line item budgets for each year of the proposed project period as a single spreadsheet table, using the Section B Budget Categories of the SF-424A and breaking down sub-categorical costs.

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[89] See *National Standards for Culturally and Linguistically Appropriate Services at:* http://minorityhealth.hhs.gov/templates/browse.aspx?lvl=2&lvlID=15

Attachment 3: *Staffing Plan*

Attachment 4: *Position Descriptions*
Keep each to one page in length. Include the role, responsibilities, and qualifications of proposed project staff. It is permissible to have more than one new job description per page.

Attachment 5: *Biographical Sketches of Key Personnel*
Include biographical sketches for persons occupying the key positions not to exceed two pages in length. In the event that a biographical sketch is included for an identified individual who is not yet hired, please include a letter of commitment from that person with the biographical sketch.

Attachment 6: *Work Plan*
The work plan should include clearly written (1) goals; (2) objectives that are specific, time-framed, and measurable; (3) action steps; (4) staff responsible for each action step (including consultants); and (5) anticipated dates of completion. Please note that goals for the work plan are to be written for the entire proposed five year project period, but objectives and action steps are required only for the goals set for Year 1.

Attachment 7: *Project Organizational Chart*
The organization chart should be a one-page figure that depicts the organizational structure of only the project, not the entire organization, and it should include subcontractors and other significant collaborators.

Attachment 8: *Signed and Dated Letters of Support, Memoranda of Agreement or Understanding, and Descriptions of Proposed and Existing Contracts*
Provide any documents that describe working relationships between the applicant organization and other agencies and programs cited in the proposal. Documents that confirm actual or pending contractual agreements should clearly describe the roles of the subcontractors. Letters of support and memoranda of agreement or understanding should be specific in indicating a commitment to the proposed project and detail in-kind services, staff, space, equipment, etc. All such letters and memoranda must be signed and dated.

Attachment 9: *Cultural and Linguistic Factors Competency Statement*
The Health Resources and Services Administration (HRSA) envisions optimal health for all, supported by a health care system that assures access to comprehensive, culturally competent, quality care.

HRSA defines cultural and linguistic competence as a set of congruent behaviors, attitudes, and policies that come together in a system, organization, or among professionals and enable that system, organization, or those professionals to work effectively in cross-cultural and linguistically diverse situations. Healthcare providers funded through HRSA grants need to be alert to the importance of cross-cultural and language-appropriate communications, as well as general health literacy issues. HRSA supports and promotes a unified health communication perspective that addresses cultural competency, limited English proficiency, and health literacy in an integrated approach in order to develop the skills and abilities needed by HRSA-funded providers and staff to deliver the best quality health care effectively to the diverse populations they serve.

HRSA is committed to ensuring access to quality health care for all. Quality care means access to services, information, and materials delivered by competent providers in a manner that factor in the language needs, cultural richness, and diversity of populations served. Quality also means that, where appropriate, data collection instruments used should adhere to culturally competent and linguistically appropriate norms. For additional information and guidance, refer to the National Standards for Culturally and Linguistically Appropriate Services in Health Care published by the U.S. Department of Health and Human Services.[90]

Wherever appropriate, describe the program's or institution's strategic plan, policies, and initiatives that demonstrate a commitment to providing culturally and linguistically competent health care and developing culturally and linguistically competent health care providers, faculty, staff, and program participants. This includes participation in, and support of programs that focus on cross-cultural health communication approaches as strategies to educate health care providers serving diverse patients, families, and communities.

Wherever appropriate identify programs that work to (1) improve medication compliance of patients, and (2) improve patient understanding regarding health conditions and (3) improve the ability of the patient to manage their condition. Wherever appropriate, describe a plan to recruit and retain key staff with demonstrated experience serving the specific target population and familiarity with the culture and language of the particular communities served.

Wherever appropriate, describe the program or institution's strategic plan, policies, and initiatives that demonstrate a commitment to serving the specific target population and familiarity with the culture and literacy level of the particular target group. Wherever appropriate, present a summary of specific training, and /or learning experiences to develop knowledge and appreciation of how culture and language influences health literacy improvement and the delivery of high quality, effective and predictably safe healthcare services.

Attachment 10: *Statement of Consistency with Healthy People 2020*
Applicants must summarize the relationship of their projects and identify which of their programs objectives and/or sub-objectives relate to the goals of the Healthy People 2020 initiative. Refer to Section VI. 2 for further information.

Attachment 11: *Other Relevant Documents*
Include here any other documents that are relevant to the application and or referenced in the application.

3. Submission Dates and Times

Application Due Date
The due date for applications under this funding opportunity announcement is **April 16, 2012** *at 8:00 P.M. ET*. Applications completed online are considered formally submitted when the application has been successfully transmitted electronically by your organization's Authorized Organization Representative (AOR) through Grants.gov and has been validated by Grants.gov on or before the deadline date and time.

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[90] See *National Standards for Culturally and Linguistically Appropriate Services at:*
http://minorityhealth.hhs.gov/templates/browse.aspx?lvl=2&lvlID=15

Receipt acknowledgement: Upon receipt of an application, Grants.gov will send a series of email messages advising you of the progress of your application through the system. The first will confirm receipt in the system; the second will indicate whether the application has been successfully validated or has been rejected due to errors; the third will be sent when the application has been successfully downloaded at HRSA; and the fourth will notify the applicant of the Agency Tracking Number assigned to the application.

The Chief Grants Management Officer (CGMO) or designee may authorize an extension of published deadlines when justified by circumstances such as natural disasters (e.g., floods or hurricanes) or other disruptions of services, such as a prolonged blackout. The CGMO or designee will determine the affected geographical area(s).

Late applications: Applications which do not meet the criteria above are considered late applications and will not be considered in the current competition.

4. Intergovernmental Review

The Special Projects of National Significance Program is a program subject to the provisions of Executive Order 12372, as implemented by 45 CFR 100. Executive Order 12372 allows States the option of setting up a system for reviewing applications from within their States for assistance under certain federal programs. Application packages made available under this funding opportunity will contain a listing of States which have chosen to set up such a review system, and will provide a State Single Point of Contact (SPOC) for the review. Information on states affected by this program and State Points of Contact may also be obtained from the Grants Management Specialist listed in the Agency Contact(s) section, as well as from the following Web site: http://www.whitehouse.gov/omb/grants_spoc.

All applicants other than federally recognized Native American Tribal Groups should contact their SPOC as early as possible to alert them to the prospective applications and receive any necessary instructions on the State's process used under this Executive Order.

Letters from the SPOC in response to Executive Order 12372 are due sixty days after the application due date.

5. Funding Restrictions

Applicants responding to this announcement may request funding for a project period of up to five (5) years, at no more than $550,000 per year. Awards to support projects beyond the first budget year will be contingent upon Congressional appropriation, satisfactory progress in meeting the project's objectives, and a determination that continued funding would be in the best interest of the Federal Government.

Funds under this announcement may not be used for the following purposes:

1) To directly provide health care or testing services that are billable to third party payers (e.g., private health insurance, prepaid health plans, Medicaid, Medicare, other Ryan White Program funding including ADAP);
2) To directly provide health care services that duplicate existing services;

3) Purchase, construction of new facilities or capital improvements to existing facilities;
4) Purchase or improvement to land;
5) Purchase vehicles;
6) Fundraising expenses;
7) Lobbying activities and expenses;
8) Reimbursement of pre-award costs;
9) International travel; and/or
10) Cash payments to intended service recipients, as opposed to various non-cash incentives to encourage participation in evaluation activities.

SPNS funding may not be used to supplant or supplement concurrent Ryan White activities or services already funded under any other Part grants. Funds awarded under this grant may not be used for direct services, including HIV care and counseling and testing, that are billable to third party payers.

Salary Limitation: The Consolidated Appropriations Act, 2012 (P.L. 112-74) enacted December 23, 2011, limits the salary amount that may be awarded and charged to HRSA grants and cooperative agreements. Award funds may not be used to pay the salary of an individual at a rate in excess of Executive Level II. The Executive Level II salary of the Federal Executive Pay scale is $179,700. This amount reflects an individual's base salary exclusive of fringe and any income that an individual may be permitted to earn outside of the duties to the applicant organization. This salary limitation also applies to subawards/subcontracts under a HRSA grant or cooperative agreement.

Per Division F, Title II, Section 503 of the Consolidated Appropriations Act, 2012 (P.L. 112-74) enacted December 23, 2011 (a) No part of any appropriation contained in this Act or transferred pursuant to section 4002 of Public Law 111-148 shall be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, electronic communication, radio, television, or video presentation designed to support or defeat the enactment of legislation before the Congress or any State or local legislature or legislative body, except in presentation to the Congress or any State or local legislature itself, or designed to support or defeat any proposed or pending regulation, administrative action, or order issued by the executive branch of any State or local government, except in presentation to the executive branch of any State or local government itself. (b) No part of any appropriation contained in this Act or transferred pursuant to section 4002 of Public Law 111-148 shall be used to pay the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or Executive order proposed or pending before the Congress or any State government, State legislature or local legislature or legislative body, other than for normal and recognized executive-legislative relationships or participation by an agency or officer of a State, local or tribal government in policymaking and administrative processes within the executive branch of that government. (c) The prohibitions in subsections (a) and (b) shall include any activity to advocate or promote any proposed, pending or future Federal, State or local tax increase, or any proposed, pending, or future requirement or restriction on any legal consumer product, including its sale or marketing, including but not limited to the advocacy or promotion of gun control.

Per Division F, Title II, Section 523 of the Consolidated Appropriations Act, 2012 (P.L. 112-74)

enacted December 23, 2011, no funds appropriated in this Act shall be used to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

6. Other Submission Requirements

As stated in Section IV.1, except in very rare cases HRSA will no longer accept applications in paper form. Applicants submitting for this funding opportunity are *required* to submit *electronically* through Grants.gov. To submit an application electronically, please use the APPLY FOR GRANTS section at http://www.grants.gov. When using Grants.gov you will be able to download a copy of the application package, complete it off-line, and then upload and submit the application via the Grants.gov site.

It is essential that your organization *immediately register* in Grants.gov and become familiar with the Grants.gov site application process. If you do not complete the registration process you will be unable to submit an application. The registration process can take up to one month.

To be able to successfully register in Grants.gov, it is necessary that you complete all of the following required actions:

- Obtain an organizational Data Universal Numbering System (DUNS) number
- Register the organization with Central Contractor Registry (CCR)
- Identify the organization's E-Business Point of Contact (E-Biz POC)
- Confirm the organization's CCR "Marketing Partner ID Number (M-PIN)" password
- Register and approve an Authorized Organization Representative (AOR)
- Obtain a username and password from the Grants.gov Credential Provider

Instructions on how to register, tutorials and FAQs are available on the Grants.gov web site at http://www.grants.gov. Assistance is also available 24 hours a day, 7 days a week (excluding federal holidays) from the Grants.gov help desk at support@grants.gov or by phone at 1-800-518-4726. Applicants should ensure that all passwords and registration are current well in advance of the deadline.

It is incumbent on applicants to ensure that the AOR is available to submit the application to HRSA by the published due date. HRSA will not accept submission or re-submission of incomplete, rejected, or otherwise delayed applications after the deadline. Therefore, you are urged to submit your application in advance of the deadline. If your application is rejected by Grants.gov due to errors, you must correct the application and resubmit it to Grants.gov before the deadline date and time. Deadline extensions will not be provided to applicants who do not correct errors and resubmit before the posted deadline.

If, for any reason, an application is submitted more than once prior to the application due date, HRSA will only accept the applicant's last validated electronic submission prior to the application due date as the final and only acceptable submission of any competing application submitted to Grants.gov.

Tracking your application: It is incumbent on the applicant to track their application by using the Grants.gov tracking number (GRANTXXXXXXXX) provided in the confirmation email from Grants.gov. More information about tracking your application can be found at

https://apply07.grants.gov/apply/checkApplStatus.faces. Be sure your application is validated by Grants.gov prior to the application deadline.

V. Application Review Information

1. Review Criteria

Procedures for assessing the technical merit of applications have been instituted to provide for an objective review of applications and to assist the applicant in understanding the standards against which each application will be judged. Critical indicators have been developed for each review criterion to assist the applicant in presenting pertinent information related to that criterion and to provide the reviewer with a standard for evaluation. Review criteria are outlined below with specific detail and scoring points.

Review Criteria are used to review and rank applications. The *Special Projects of National Significance Program* has six (6) review criteria:

Criterion 1: Need (10 Points)
The extent to which the application demonstrates the problem and associated contributing factors to the problem.

This corresponds to the Introduction and Needs Assessment sections of the Narrative.

i. Introduction
- Strength and clarity of the applicant's succinct description of the roles and activities of the Evaluation and Technical Assistance Center (ETAC) in achieving the purpose of the initiative to improve timely entry, engagement and retention in quality HIV primary care for transgender women of color.
- Strength and clarity of the applicant's brief descriptions of the applicant organization, any collaborating organizations and the multi-site evaluation, technical assistance and capacity building services the ETAC will provide.

ii. Needs Assessment
- Extent to which the summary of the literature demonstrates a comprehensive understanding of the issues that interfere with identifying, engaging and retaining transgender women of color living with HIV infection in quality HIV primary care.
- Strength and clarity of the discussion of factors driving incidence and prevalence rates of HIV infection among transgender women of color, using the most recent, available, *transgender*-specific data (i.e., non-MSM).
- Strength and clarity of the discussion of HIV counseling and testing of transgender women of color, including the challenges to identifying those who are at high risk of HIV infection or are infected with HIV but are unaware of their HIV status; are aware of their HIV infection but have never been engaged to care; are aware but have refused referral to care; or have dropped out of care; and what strategies may be used to overcome these challenges.
- Strength and clarity of the description of the issues that interfere with engaging and retaining transgender women of color living with HIV infection in quality HIV

primary care, including those who are newly diagnosed during the project, and what strategies may be used to overcome them.

- Strength and clarity of the summary of the policy, financial, structural, and clinical issues related to improving timely entry, access to and retention in quality HIV care for transgender women of color.

Criterion 2: Response (25 Points)
The extent to which the proposed project responds to the Purpose of the initiative as described earlier in this funding opportunity announcement. The strength of the proposed goals and objectives and their relationship to the identified project. The extent to which the activities (scientific or other) described in the application are capable of addressing the problem and attaining the project objectives.

This corresponds to the Methodology, Work Plan and Resolution of Challenges sections of the Narrative.

i. **Methodology**
- Strength and feasibility of the applicant's proposed plan for the provision of technical assistance (TA) to the demonstration projects over the course of the initiative, including a routine means of TA needs assessment.
- Strength and feasibility of the applicant's description of anticipated TA needs and the means by which they will be addressed.
- Feasibility of the applicant's plan to review the demonstration projects' plans to safeguard the privacy and confidentiality of study participants, and their documented procedures for the electronic and physical protection of study participant information and data, and a means to address deficits
- Strength and clarity of the description of the elements of a site visit protocol for annual site visits to the demonstration projects.
- Strength of the plan for providing capacity building relating to the provision of quality clinical and culturally competent HIV primary care to transgender women of color.
- Strength and feasibility of the proposed scope and delivery methods for capacity building activities during the initiative.
- Strength and clarity of the identification of areas where improvements are needed in clinical care and ancillary service delivery based upon the research literature, and feasibility of proposed methods to address deficits.
- Strength of the approach to the provision of culturally and linguistically competent health care and social services to transgender people of color, with a focus on racial, ethnic, sexual and gender minority disparities faced by this population.
- Evidence of experience of proposed project staff in logistical planning and implementation of national meetings.

ii. **Work Plan**
- Strength, clarity and feasibility of the Work Plan and its goals for the 5-year project period (**Attachment 6**).
- Extent to which the goals of the Work Plan address the program requirements the applicant described in the Methodology section of the Narrative.

- Evidence the objectives for Year 1 are complete, specific to each goal, time-framed, and measurable.
- Evidence the Work Plan includes each planning, implementation and evaluation activity, and identifies the staff responsible to accomplish each step.

iii. Resolution of Challenges
- Extent to which possible challenges that are likely to be encountered during the planning and implementation of the project are identified.
- Extent to which realistic and appropriate responses to be used to resolve those challenges are described.

Criterion 3: Evaluative Measures (20 points)
The strength and effectiveness of the methods proposed to monitor and evaluate the project results. Evaluative measures must be able to assess the extent to which the program objectives have been met and the extent to which these can be attributed to the project.

This corresponds to the evaluation methodology described in the Methodology section of the Narrative.

- Strength and feasibility of the proposed plan for a rigorous national multi-site evaluation across demonstration projects that will have maximum impact on practice and policy affecting timely entry, access to and retention in quality HIV primary care for transgender women of color.
- Strength and clarity of the anticipated evaluation questions for assessing the effectiveness of demonstration project interventions.
- Strength and feasibility of the methodology that will be used to conduct the multi-site evaluation and its rationale for selection.
- Strength and clarity of the outline for the outcome, process and cost elements of the multi-site evaluation, and possible measures for them.
- Strength of the proposed focused studies of interest relating to transgender women of color, including their rationale and possible impact.

Criterion 4: Impact (10 Points)
The feasibility and effectiveness of plans for dissemination of project results and whether the project results may be national in scope.

This corresponds to the Methodology and Work Plan sections of the Narrative.

- Strength of approach in leading publication and dissemination efforts for the initiative's findings and lessons learned.
- Clarity of the discussion of how a publications and disseminations committee would operate.
- Strength of the proposed plan for dissemination of project findings, best practices and lessons learned to target audiences at appropriate venues including national conferences, and policymakers.

Criterion 5: Resources/Capabilities (25 Points)
The extent to which project personnel (including consultants and sub-contractors) are qualified

by training and/or experience to implement and carry out the project. The capabilities of the applicant organization, including quality and availability of facilities and personnel to fulfill the needs and requirements of the proposed project.

This corresponds to the Evaluation Capacity and Organizational Information sections of the Narrative.

i. Evaluation Capacity
- Evidence of demonstrated expertise in both engagement and retention in HIV treatment and transgender clinical health.
- Evidence of capacity to conduct a comprehensive multi-site evaluation and the multi-site participant cohort as a whole.
- Extent of experience, skills, training and knowledge of proposed key project staff (including any consultants and subcontractors, if applicable) in achieving scientific excellence and evaluation integrity in conducting a multi-site evaluation of national scope that will have maximum impact on practice and policy affecting timely entry, access to and retention in quality HIV primary care for transgender women of color.
- Strength and clarity of the approach to working collaboratively with demonstration projects in leading data collection and reporting efforts for the multi-site evaluation and additional focused evaluation studies.
- Extent of experience, skills, training and knowledge of proposed key project staff (including any consultants and subcontractors, if applicable) in designing and implementing public health program evaluations, specifically quantitative and qualitative outcome and process evaluations and cost studies of innovative HIV access and retention projects.
- Evidence of any specific experience of proposed key project staff in the evaluation of programs reaching those who are unaware of their HIV status, as well as engaging and retaining those newly diagnosed in quality HIV primary care.
- Evidence of any specific experience of proposed staff in the design, implementation and evaluation of programs serving transgender women of color at risk or living with HIV infection.
- Evidence of any specific experience of proposed staff in conducting focused studies related to engagement and retention in HIV treatment and transgender health, and if applicable, any published materials and presentations.
- Strength of applicant's capacity to provide leadership and technical assistance to demonstration sites for the multi-site and local evaluations.
- Extent of experience of the proposed staff (including consultants' and subcontractors', if applicable) in providing technical assistance and capacity building to HIV primary care and social service organizations.
- Evidence of any expertise in transgender health, with a focus on clinical consultation and cultural competencies.
- Extent of experience of proposed key project staff (including any consultants and subcontractors) in collaborative writing and publishing study findings in peer reviewed journals.
- Extent of experience of proposed key project staff (including any consultants and subcontractors) in making presentations to local communities, State and national conferences and to policy makers.

- Extent of experience of proposed key project staff (including any consultants and subcontractors) in logistical planning, implementation and evaluation of national meetings.
- Evidence the applicant agrees to submit proof of IRB approvals and renewals for all client-level data collection instruments, informed consents and evaluation materials to the SPNS program on an annual basis.
- Evidence of any training in human subjects research protection by proposed key project staff of the applicant.
- Strength of the plan to safeguard patients' privacy and confidentiality, and documented procedures for electronically and physically protecting the privacy of patient information and data, in accordance with HIPAA regulations and human subjects research protections.
- Strength of the plans for the initiative's website, its data portal and the documented procedures for the electronic and physical protection of participant information and data.
- Strength of the proposed system or methods to be used for tracking the demonstration projects' IRB approvals and annual renewals for the multi-site evaluation, their local evaluations and any other related studies and reporting them to SPNS Program staff.

ii. **Organizational Information**
- The extent to which the applicant organization's mission, organizational structure, the quality and availability of facilities and personnel, and the scope of current activities contribute to its ability to conduct the proposed project and meet the expectations of the program requirements.
- Strength of the applicant's capacity to conduct the required multi-site evaluation, technical assistance and capacity building activities described earlier in this announcement.
- Evidence of the capacity of the applicant's management information system (MIS) to support a comprehensive multi-site evaluation in the collection, reporting and secure storage of client-level data.
- Evidence of a project organizational chart, depicting only the project, not the entire organization, and including subcontractors and other significant collaborators (**Attachment 7**).
- If applicable, extent to which the roles and responsibilities of consultants and/or subcontractors to be used to carry out aspects of the proposed project are appropriate.
- If applicable, the appropriateness of signed and dated letters or memoranda of agreement or understanding from current and proposed collaborating organizations and individuals to fulfill the goals and objectives of the project (**Attachment 8**).
- Evidence of the applicant organization's cultural competency capabilities (**Attachment 9**).

Criterion 6: Support Requested (10 Points)
The reasonableness of the proposed budget for each year of the project period in relation to the objectives, the complexity of the research activities, and the anticipated results. The extent to which costs, as outlined in the budget and required resources sections, are reasonable given the scope of work. The extent to which key personnel have adequate time devoted to the project to achieve project objectives.

This corresponds to the Budget, Budget Justification, and Staffing Plan sections.

i. Budget and Budget Justification
- Appropriateness of the line item budgets for each year of the project period (**Attachment 2**) as they relate to the proposed work plan.
- Appropriateness and clarity of the budget justification narrative's support for each line item.
- Evidence the line item budgets specify allocations for staffing in percentages of full-time equivalents (FTEs) that are adequate for the proposed activities for each year of the project.
- If applicable, the extent to which contracts for proposed subcontractors and consultants are clearly described in terms of contract purposes; how costs are derived; and that payment mechanisms and deliverables are reasonable and appropriate.
- Evidence the budgets allocate sufficient support to meet the logistical meeting arrangements and long distance travel expenses associated with the two SPNS grantee meetings in Washington, DC.

ii. Staffing Plan
- The extent to which the staffing plan is consistent with the project description and project activities (**Attachment 3**).
- Evidence the staffing plan includes key personnel with the skills, knowledge, education and training required to successfully implement all of the project activities throughout the project as described in the work plan.
- Extent to which the time allocated for key staff is consistent with their expected workload and goals and objectives of the project.
- Strength and appropriateness of the job descriptions for key staff (**Attachment 4**).
- Strength and appropriateness of the biographical sketches (**Attachment 5**)

2. Review and Selection Process

The Division of Independent Review is responsible for managing objective reviews within HRSA. Applications competing for federal funds receive an objective and independent review performed by a committee of experts qualified by training and experience in particular fields or disciplines related to the program being reviewed. In selecting review committee members, other factors in addition to training and experience may be considered to improve the balance of the committee, e.g., geographic distribution. Each reviewer is screened to avoid conflicts of interest and is responsible for providing an objective, unbiased evaluation based on the review criteria noted above. The committee provides expert advice on the merits of each application to program officials responsible for final selections for award.

Applications that pass the initial HRSA eligibility screening will be reviewed and rated by a panel based on the program elements and review criteria presented in relevant sections of this funding opportunity announcement. The review criteria are designed to enable the review panel to assess the quality of a proposed project and determine the likelihood of its success. The criteria are closely related to each other and are considered as a whole in judging the overall quality of an application.

3. Anticipated Announcement and Award Dates

It is anticipated that awards will be announced prior to the start date of September 1, 2012.

VI. Award Administration Information

1. Award Notices

Each applicant will receive written notification of the outcome of the objective review process, including a summary of the expert committee's assessment of the application's strengths and weaknesses, and whether the application was selected for funding. Applicants who are selected for funding may be required to respond in a satisfactory manner to Conditions placed on their application before funding can proceed. Letters of notification do not provide authorization to begin performance.

The Notice of Award sets forth the amount of funds granted, the terms and conditions of the award, the effective date of the award, the budget period for which initial support will be given, the non-federal share to be provided (if applicable), and the total project period for which support is contemplated. Signed by the Grants Management Officer, it is sent to the applicant's Authorized Organization Representative, and reflects the only authorizing document. It will be sent prior to the start date of September 1, 2012.

2. Administrative and National Policy Requirements

Successful applicants must comply with the administrative requirements outlined in 45 CFR Part 74 Uniform Administrative Requirements for Awards and Subawards to Institutions of Higher Education, Hospitals, Other Nonprofit Organizations, and Commercial Organizations or 45 CFR Part 92 Uniform Administrative Requirements For Grants And Cooperative Agreements to State, Local, and Tribal Governments, as appropriate.

HRSA grant and cooperative agreement awards are subject to the requirements of the HHS Grants Policy Statement (HHS GPS) that are applicable based on recipient type and purpose of award. This includes, as applicable, any requirements in Parts I and II of the HHS GPS that apply to the award. The HHS GPS is available at http://www.hrsa.gov/grants/. The general terms and conditions in the HHS GPS will apply as indicated unless there are statutory, regulatory, or award-specific requirements to the contrary (as specified in the Notice of Award).

Human Subjects Protection
Federal regulations (45 CFR 46) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained. If research involving human subjects is anticipated, you must meet the requirements of the DHHS regulations to protect human subjects from research risks as specified in the Code of Federal Regulations, Title 45 – Public Welfare, Part 46 – Protection of Human Subjects (45 CFR 46), available online at www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html.

Trafficking in Persons

Awards issued under this funding opportunity announcement are subject to the requirements of Section 106 (g) of the Trafficking Victims Protection Act of 2000, as amended (22 U.S.C. 7104). For the full text of the award term, go to http://www.hrsa.gov/grants/trafficking.html. If you are unable to access this link, please contact the Grants Management Specialist identified in this funding opportunity to obtain a copy of the Term.

Smoke-Free Workplace

The Public Health Service strongly encourages all award recipients to provide a smoke-free workplace and to promote the non-use of all tobacco products. Further, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children.

Cultural and Linguistic Competence

HRSA programs serve culturally and linguistically diverse communities and multiple cultures. Although race and ethnicity are often thought to be dominant elements of culture, HRSA funded programs embrace a broader definition to include language, gender, socio-economic status, sexual orientation and gender identity, physical and mental capacity, age, religion, housing status, and regional differences. Organizational behaviors, practices, attitudes, and policies across all HRSA-supported entities respect and respond to the cultural diversity of communities, clients and students served. HRSA is committed to ensuring access to quality health care for all. Quality care means access to services, information, materials delivered by competent providers in a manner that factors in the language needs, cultural richness, and diversity of populations served. Quality also means that, where appropriate, data collection instruments used should adhere to culturally competent and linguistically appropriate norms. For additional information and guidance, refer to the National Standards for Culturally and Linguistically Appropriate Services in Health Care (CLAS) published by HHS and available online at http://minorityhealth.hhs.gov/templates/browse.aspx?lvl=2&lvlID=15. Additional cultural competency and health literacy tools, resources and definitions are available online at http://www.hrsa.gov/culturalcompetence and http://www.hrsa.gov/healthliteracy.

Healthy People 2020

Healthy People 2020 is a national initiative led by HHS that sets priorities for all HRSA programs. The initiative has four overarching goals: (1) attain high-quality, longer lives free of preventable disease, disability, injury, and premature death; (2) achieve health equity, eliminate disparities, and improve the health of all groups; (3) create social and physical environments that promote good health for all; and (4) promote quality of life, healthy development, and healthy behaviors across all life stages. The program consists of 42 topic areas, containing measurable objectives. HRSA has actively participated in the work groups of all the topic areas, and is committed to the achievement of the Healthy People 2020 goals. More information about Healthy People 2020 may be found online at http://www.healthypeople.gov/.

Health IT

Health information technology (Health IT) provides the basis for improving the overall quality, safety and efficiency of the health delivery system. HRSA endorses the widespread and consistent use of health IT, which is the most promising tool for making health care services more accessible, efficient and cost effective for all Americans.

Related Health IT Resources:
- [Health Information Technology (HHS)](#)
- [What is Health Care Quality and Who Decides? (AHRQ)](#)

3. Reporting

The successful applicant under this funding opportunity announcement must comply with the following reporting and review activities:

a. **Audit Requirements**
   Comply with audit requirements of Office of Management and Budget (OMB) Circular A-133. Information on the scope, frequency, and other aspects of the audits can be found on the Internet at http://www.whitehouse.gov/omb/circulars_default.

b. **Payment Management Requirements**
   Submit a quarterly electronic Federal Financial Report (FFR) Cash Transaction Report via the Payment Management System. The report identifies cash expenditures against the authorized funds for the grant or cooperative agreement. The FFR Cash Transaction Reports must be filed within 30 days of the end of each calendar quarter. Failure to submit the report may result in the inability to access award funds. Go to http://www.dpm.psc.gov for additional information.

c. **Status Reports**
   1) **Federal Financial Report**. The Federal Financial Report (SF-425) is required within 90 days of the end of each budget period. The report is an accounting of expenditures under the project that year. Financial reports must be submitted electronically through EHB. More specific information will be included in the Notice of Award.

   2) **Progress Report**(s). The awardee must submit a progress report to HRSA on a semi-annual basis. Timely submission and HRSA approval of your Federal Financial Report (FFR) and your Progress Report for the prior budget period initiates a new budget period and the release of the next year's funds. Further information on specific content will be provided in the award notice.

   3) **Final Report**. A final report is due within 90 days after the project period ends. Further information on specific content will be provided post-award. The final report must be submitted on-line by awardees in the Electronic Handbooks system at https://grants.hrsa.gov/webexternal/home.asp.

d. **Transparency Act Reporting Requirements**
   New awards ("Type 1") issued under this funding opportunity announcement are subject to the reporting requirements of the Federal Funding Accountability and Transparency Act (FFATA) of 2006 (Pub. L. 109–282), as amended by section 6202 of Public Law 110–252, and implemented by 2 CFR Part 170. Grant and cooperative agreement recipients must report information for each first-tier subaward of $25,000 or more in federal funds and executive total compensation for the recipient's and subrecipient's five most highly compensated executives as outlined in Appendix A to 2 CFR Part 170 (FFATA details are available online at http://www.hrsa.gov/grants/ffata.html).

Competing continuation awardees may be subject to this requirement and will be so notified in the Notice of Award.

VII. Agency Contacts

Applicants may obtain additional information regarding business, administrative, or fiscal issues related to this funding opportunity announcement by contacting:

Tammy Jeffs, Grants Management Specialist
Attn: Enhancing Engagement and Retention in Quality HIV Care for Transgender Women of Color- Evaluation and Technical Assistance Center (HRSA-12-101)
HRSA Division of Grants Management Operations, OFAM
Parklawn Building, Room 11-03
5600 Fishers Lane
Rockville, MD 20857
Telephone: (301) 443-5419
Fax: (301) 443-6343
Email: TJeffs@hrsa.gov

Additional information related to the overall program issues and/or technical assistance regarding this funding announcement may be obtained by contacting:

Adan Cajina
Demonstration and Evaluation Branch
Attn: *Enhancing Engagement and Retention in Quality HIV Care for Transgender Women of Color – Evaluation and Technical Assistance Center* (# HRSA-12-101)
HIV-AIDS Bureau, HRSA
Parklawn Building, Room 7C-07
5600 Fishers Lane
Rockville, MD 20857
Telephone: (301) 443-3180
Fax: (301) 594-2511
Email: ACajina@hrsa.gov

Applicants may need assistance when working online to submit their application forms electronically. Applicants should always obtain a case number when calling for support. For assistance with submitting the application in Grants.gov, contact Grants.gov 24 hours a day, seven days a week, excluding federal holidays at:

Grants.gov Contact Center
Telephone: 1-800-518-4726
E-mail: support@grants.gov

VIII. Tips for Writing a Strong Application

A concise resource offering tips for writing proposals for HHS grants and cooperative agreements can be accessed online at: http://www.hhs.gov/asrt/og/grantinformation/apptips.html.